

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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<b>IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION</b>	<b>:</b>	<b>Master Docket: Misc. No. 21-mc-1230-JFC</b>
	<b>:</b>	
	<b>:</b>	<b>MDL No. 3014</b>
	<b>:</b>	
<b>This Document Relates to:</b>	<b>:</b>	<b>CONSOLIDATED THIRD AMENDED</b>
<b>All Actions</b>	<b>:</b>	<b>CLASS ACTION COMPLAINT FOR</b>
	<b>:</b>	<b>ECONOMIC LOSSES</b>

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- Ex. 164            PDF – Royal Philips’ Global Website – Philips Wordmark



1. Plaintiffs William Brengle, Gregory Byrge, Brenda De Journette, Mark Goodenough, Ivy Creek of Tallapoosa LLC d/b/a Lake Martin Community Hospital, Elmore Community Hospital Rural Health Association d/b/a Elmore Community Hospital, Gail Gilliard-Gunter, Jeffrey Groudan, Russell Autry, Paul Bailey, Michael Bastasch, Mary Campbell, Matthew Krantz, Don Luenebrink, Douglas Mest, Lisa Mitrovich, Patrick Nielson, Jimy Ruiz, Robert Waybright, Kenneth Archuleta, Sylvia McDaniel, Natalie Gottlieb, Paul Rohan, Jose Toscano, Anthony George, Bert Gibbons, Donald Boyd, Kenneth Dzierzanowski, Tara Fields, Dennis Morris, Glenn Paraday, Barbara Smith, Rudolph J. Childre Jr., Eric Michael Davis, Roy Fultz, Dephine Lewis, Jared Luke, John Mercure, Richard Sizemore, Chris Brown, Chad Savoure, Danny Baran, Shannon Brooks, Debbie Rootberg, Diane Anderson, Steven Clark, Steve Abarr, Asherdee Diamond, Jeff Wilson, Sharon Cathers, John Ratliff, Paul Baudoin, John Couch, Susan Martin, Ronald Romas, Julie Barrett, Peter Barrett, Doris Margoles, Ryan Schwartz, Pete Bellotti, Daniel F. Conley, Marc Whaley, William Wilks, Prinna Boudreau, Robert Bruce Mold, Mary Godeaux, James Jefferson Rankin, Grady Tucker, Jr., John Young, Danny David, Elizabeth Lemus, Elaine Lizotte, William Vlahos, Susanne Dennis, Joseph Ryan, Aaron Taylor, Mark Bossey, Bruce Ginsberg, Carl Gold, Jeffrey Bartalo, Patricia Flick, Jack Giordano, Rachel Hock, Vincent Stefanini, Matthew Ward, Jason Mcelyea, John Masington, Marilyn Sweeney, Antonio Perez Bonano, Diane Lamontagne, Mark Weiner, William Anderson, Adam Cote, Murray Craig, Sarah Claunch, Ronald Cline, Raul Deleon, Sarah Lowney, Sabrina Malone, Paul Panzera, Roland Rendon, Michael Tobin, Ronald Turner, David Martin, Elizabeth Heilman, Penny Hudson, Beth Rodgers, Cameron Rose, Jose Lopez, Robert Peebles, David Bays, Brent Hamlin, Donald Rucker, Robert Matters, ASEA/AFSCME Local 52 Health Benefits Trust, Ohio Carpenters' Health Fund, and MSP Recovery Claims Series, LLC, MSPA Claims 1,

LLC, MAO-MSO Recovery II, LLC, Series PMPI, MSP Recovery Claims Series 44, LLC, MSP Recovery Claims PROV, Series LLC, and MSP Recovery Claims CAID, Series LLC, individually and on behalf of all others similarly situated, through the undersigned counsel, allege as follows:

## **I. NATURE OF THE ACTION**

2. Defendant Koninklijke Philips N.V. (“Royal Philips”) is a Dutch multinational company that is the global head of the “Philips” enterprise, which bills itself as “a diverse team made up of some 80,000 individuals across over 100 countries, all with different backgrounds, perspectives and experiences.”<sup>1</sup> Royal Philips controls and oversees all aspects of the Philips businesses around the world, going to great lengths to ensure there is a unity of purpose and vision, consistent execution of company procedures, policies, and goals, and, importantly, maintenance and protection of the valuable “Philips” brand. In addition to Royal Philips, Defendants, Philips North America LLC (“Philips NA”), Philips Holding USA Inc. (“Philips USA”), Philips RS North America LLC (“Philips RS”), and Philips RS North America Holding Corporation (“Philips RS Holding”) are essential parts of the Philips family that, along with other Philips’ entities, engaged in the wrongful conduct at issue in this litigation. These Defendants are referred to collectively herein as “Philips” or the “Philips Defendants.” At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and references to “Philips” refer to each Philips Defendant individually and collectively.

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<sup>1</sup> See Royal Philips “About us” webpage, <https://www.philips.com/a-w/about.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “1”). All attached Exhibits and reference material are incorporated as if fully stated herein.

3. Royal Philips boasts on its website, [www.philips.com](https://www.philips.com)<sup>2</sup>: “Over the past decade we have transformed into a focused leader in health technology.... At Philips, our purpose is to improve people’s health and well-being through meaningful innovation.”<sup>3</sup> As part of that business, Philips manufactures and sells certain lines of products that are intended to help people breathe. These include Continuous Positive Airway Pressure (“CPAP”) and Bilevel Positive Airway Pressure (“BiPAP”) machines, which are commonly used to treat sleep apnea, and mechanical ventilators (“ventilators”), which treat respiratory failure. The primary function of these devices is to blow air into patients’ airways. CPAP and BiPAP machines are intended for use during sleep while ventilators are used continuously when needed.

4. Because these machines are used during sleep, Philips designed them to include sound-dampening foam intended to reduce noise emitted from the motors in the devices. Unfortunately, Philips designed its devices to include polyester-based polyurethane (“PE-PUR”) foam, which Philips knew for many years, among other things, is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. This can result in degradation of the foam and off-gassing of volatile organic compounds (“VOCs”).

5. On June 14, 2021, Philips, through multiple of its entities, including Royal Philips and Philips RS, announced a recall of approximately 11 million of its CPAP and BiPAP

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<sup>2</sup> The landing (*i.e.*, opening) page for Royal Philips’ website contains a copyright for Royal Philips. See <https://www.philips.com/global> (“© Koninklijke Philips N.V., 2004 - 2022. All rights reserved.”) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “2”). When accessing the Royal Philips website from the United States, users are automatically redirected to <https://www.usa.philips.com/> (last accessed Oct. 3, 2022). The redirected page also contains a copyright for Royal Philips. See <https://www.usa.philips.com/> (“© Koninklijke Philips N.V., 2004 - 2022. All rights reserved.”) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “3”).

<sup>3</sup> Royal Philips “About us” webpage (Exhibit “1” hereto).

machines and ventilators in the United States that were manufactured with PE-PUR foam from 2008 until the date of the recall (the “Recall”). All of these recalled products (individually referred to herein as a “Recalled Device,” or collectively, as the “Recalled Devices”) are defective because they contain PE-PUR foam.

6. The Recalled Devices are:

- E30
- DreamStation ASV
- DreamStation ST, AVAPS
- SystemOne ASV4
- C Series ASV, S/T, AVAPs
- OmniLab Advanced Plus
- SystemOne (Q Series)
- DreamStation CPAP, Auto CPAP, BiPAP
- DreamStation Go CPAP, APAP
- Dorma 400, 500 CPAP
- REMStar SE Auto CPAP
- Trilogy 100 and 200
- Garbin Plus, Aeris, LifeVent
- A-Series BiPAP Hybrid A30
- A-Series BiPAP V30 Auto
- A-Series BiPAP A40
- A-Series BiPAP A30

7. The use of PE-PUR foam in the Recalled Devices is a defect because the foam is susceptible to breaking down into particles which may then be inhaled or ingested by the user, and may emit VOCs that can also be inhaled, resulting in “serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.”<sup>4</sup>

8. Philips was aware of problems with the PE-PUR foam in the Recalled Devices dating as far back as 2008 when it began receiving numerous complaints from customers including complaints containing the keywords “contaminants, particles, foam, debris, airway, particulate, airpath, and black.”<sup>5</sup> In addition, beginning as far back as 2015, Philips conducted and received multiple test reports and additional data confirming that the Recalled Devices pose serious, indeed life-threatening, health risks to users, but Philips failed to timely disclose that they were defective when manufactured and sold.

9. Instead of instituting a recall immediately, Philips waited until June 2021 to issue the Recall and notify the public about the dangers of the Recalled Devices, continuing to sell defective devices and leaving users to breath in the toxic fumes and risk serious injury. In its Recall, Philips publicly announced that the PE-PUR foam may break down into particles and be inhaled or ingested, and may emit VOCs that can be inhaled, resulting in “serious injury which

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<sup>4</sup> Philips Recall Notices issued June 14, 2021 (attached hereto as Exhibit “4”).

<sup>5</sup> See FDA 483 Report issued to Philips on November 9, 2021 (hereinafter “483 Report”), redacted version available at: <https://www.fda.gov/media/154244/download> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “5”), at 12. A 483 Report from the Food and Drug Administration (“FDA”) “is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts.” FDA webpage, FDA Form 483 Frequently Asked Questions, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “6”).

can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment”<sup>6</sup> (referred to herein as the “Defect”). Philips stated that the potential risks of exposure due to such chemicals include “headache/dizziness, irritation (eyes, nose respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects.”<sup>7</sup> Philips’ announcement to doctors advised that these hazards could result in “serious injury which can be life-threatening or cause permanent impairment.”<sup>8</sup>

10. In addition, on July 22, 2021, the U.S. Food and Drug Administration (“FDA”) confirmed the severity of the issues described in the Recall and classified the Recall as Class I or “the most serious type of recall,” meaning use of the Recalled Devices “may cause serious injuries or death.”<sup>9</sup>

11. As noted above, Philips knew about the serious risks caused by the Recalled Devices long before the Recall.

12. On November 9, 2021, the FDA issued a report detailing the findings of an FDA investigation, findings that demonstrate Philips knew that the PE-PUR foam degraded into hazardous substances.<sup>10</sup> The FDA discovered emails, dating back to October 2015, to Philips from the supplier of the raw foam used to make the PE-PUR foam in the Recalled Devices

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<sup>6</sup> Philips Recall Notices issued June 14, 2021 (Exhibit “4” hereto).

<sup>7</sup> *Id.*

<sup>8</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical information for physicians (June 14, 2021), at 2, available at: [philips-recall-clinical-information-for-physicians-and-providers.pdf](#) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “7”).

<sup>9</sup> FDA Notice, “Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals,” available at: <https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “8”).

<sup>10</sup> See generally, 483 Report (Exhibit “5” hereto).

regarding PE-PUR foam degradation issues.<sup>11</sup> Additionally, the FDA found that, in November 2015, Philips engaged in preventative maintenance on certain Recalled Devices in response to PE-PUR foam degradation issues and complaints, yet failed to conduct any “further investigation, health hazard evaluation, risk analysis, or design review” on any of the Recalled Devices that use the same PE-PUR foam.<sup>12</sup> To be sure, the FDA found that “there were at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions.”<sup>13</sup> This is in addition to the detailed customer complaints that existed as far back as 2008 and the additional data Philips collected in 2015.

13. Despite knowing about the degradation and off-gassing problems with the PE-PUR foam and the associated health risks for users of the affected devices, Philips failed until many years later to disclose the Defect to consumers, hospitals, institutions, doctors, and suppliers, continuing to sell the defective products and allowing patients to use the defective products. In addition, Defendant Polymer Technologies, Inc. (“PolyTech”), a supplier of PE-PUR foam to Philips, worked with Philips to conceal these key facts from consumers so that both could continue to profit from the sales of these defective devices.

14. It was only after Philips launched its next generation of CPAP/BiPAP machines (the DreamStation 2 devices), machines that do not contain PE-PUR foam and could serve as a replacement for Recalled Devices, that Philips finally disclosed that its Recalled Devices were defective. That is, on April 26, 2021, Philips announced that its previous generation

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<sup>11</sup> *Id.* at 3, 18.

<sup>12</sup> *Id.* at 2.

<sup>13</sup> *Id.* at 3.

DreamStation products and other CPAP, BiPAP, and ventilator devices posed serious health risks to users. Philips then waited an additional seven weeks before initiating the Recall of the dangerously defective machines in the United States. Shortly thereafter, Philips expanded its recall of defective CPAP, BiPAP, and ventilator devices worldwide.<sup>14</sup>

15. Because of the increased demand for safe and effective CPAP, BiPAP, and ventilator devices at the time of the Recall, replacement machines were difficult to find and expensive, a situation that was exacerbated by a shortage of microchips for these devices. Thus, many users were forced into a Hobson's choice – continue using their Recalled Devices and expose themselves to risks of serious injury or death, or stop using their breathing devices and risk health consequences from their underlying conditions.

16. When the Recall was first announced on June 14, 2021, Philips did not offer users of the Recalled Devices any option for a replacement device.

17. On September 1, 2021, Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States, and initially, Philips estimated that it would take a year to complete the program.<sup>15</sup>

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<sup>14</sup> See, e.g., Philips website, Urgent Product Defect Correction in Australia (Recall for Product Correction in New Zealand), <https://www.philips.com.au/healthcare/e/sleep/communications/src-update> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "9") (stating that a global recall notification was issued on June 14, 2021 and that recalls specific to Australia and New Zealand were issued on July 2, 2021). As discussed, *infra*, in note 370, other impacted countries include, but are not limited to Canada, Israel, and Chile.

<sup>15</sup> See Royal Philips Press Release, Philips starts repair and/or replacement program of first-generation DreamStation devices in the US and other markets (Sept. 1, 2021), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210901-philips-starts-repair-and-replacement-program-of-first-generation-dreamstation-devices-in-the-us-in-relation-to-earlier-announced-recall-notification.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "10"); see also Philips "Ventilation News and Updates" webpage, Trilogy Remediation Update for Business Customers (June 1, 2022), <https://www.usa.philips.com/healthcare/resource-catalog/landing/experience->



18. In announcing the repair/replacement program, Royal Philips CEO Frans van Houten acknowledged that patients using Recalled Devices needed a solution and that delayed relief for them presented a problem: “We fully recognize that the timeframe for remediation of the affected devices places patients in a difficult situation.”<sup>16</sup>

19. Unfortunately for users of the recalled DreamStation devices, the repair and replacement program was negligently implemented and ineffective. DreamStation customers were not given any specifics as to how the replacement program would work nor were they told when they might receive a replacement device (a significant factor for users who relied on the machines for medical conditions). Nor did Philips provide meaningful guidance to DreamStation customers’ treating physicians. In addition, the repair and/or replacement program was limited in that it only impacted DreamStation Recalled Devices and not any other Recalled Device.

20. Each of the Plaintiffs, in whole or part, paid for or reimbursed payment for a Recalled Device and/or a device to replace a Recalled Device. The Plaintiffs would not have paid for or reimbursed payment for the Recalled Devices had they known that the PE-PUR foam in the Recalled Devices could expose users to life-threatening injuries or cause serious health problems, rendering the Recalled Devices defective and unsafe, and not fit for their intended purpose.

21. Plaintiffs, individually and on behalf of all others similarly situated who, in whole or part, paid for or reimbursed payment for the defective Recalled Devices or a device to replace a Recalled Device, seek to recover economic losses and punitive damages from Philips for breach of express warranty, breach of the implied warranty of merchantability, breach of the [catalog/sleep/communications/src-update/news/ventilation-news-and-updates](https://www.philips.com/catalog/sleep/communications/src-update/news/ventilation-news-and-updates) (last accessed Oct. 7, 2022) (attached hereto as Exhibit “11”).

<sup>16</sup> *Id.*

implied warranty of usability, the Magnuson Moss Warranty Act, fraud, the Racketeer Influenced and Corrupt Organizations (“RICO”) Act, negligent failure to recall/negligent recall, unjust enrichment, redhibition, and applicable state consumer protection statutes.<sup>17</sup>

## **II. THE PARTIES**

### **A. PLAINTIFFS**

22. Plaintiff William Brengle (“Brengle”) is a citizen of Alabama and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about September 2017, in Missouri, where he was residing at the time. Plaintiff moved to Alabama later in 2017. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$600.

23. Plaintiff Gregory Byrge (“Byrge”) is and at all relevant times was a citizen of Alabama and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about December 2017, in Alabama. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was

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<sup>17</sup> Plaintiffs reserve the right to amend this Complaint to reflect additional information uncovered through discovery and developed *via* expert testimony.

not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$150.

24. Plaintiff Brenda De Journette ("De Journette") is and at all relevant times was a citizen of Alabama and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about April 2021, in Alabama. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$500.

25. Plaintiff Mark Goodenough ("Goodenough") is and at all relevant times was a citizen of Alabama and the United States. Plaintiff paid for a Philips Respironics DreamStation 1 on or about November 2019, in Alabama. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the

Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$700.

26. Plaintiff Ivy Creek of Tallapoosa LLC d/b/a Lake Martin Community Hospital ("Lake Martin Hospital") is an Alabama Limited Liability Company with its principal place of business in Tallapoosa County, Alabama. Lake Martin Hospital is and at all relevant times was a Limited Liability Company organized and operating in Alabama and the United States. Lake Martin Hospital purchased directly from Philips RS North America LLC, f/k/a Respironics, Inc., two Philips OmniLab Advanced + continuous ventilators and two DreamStation devices for use in the hospital in Alabama. Lake Martin Hospital was unaware of the Defect at the time of purchase, and only became aware of the Defect after it learned that its devices were included in the Recall. Had Lake Martin Hospital been aware of the Defect in its Omnilab Advanced + and DreamStation devices, it would not have purchased them. Lake Martin Hospital seeks full reimbursement of all costs and damages associated with the purchase of the Recalled Devices and costs and damages associated with the Recall.

27. Plaintiff Elmore Community Hospital Rural Health Association d/b/a Elmore Community Hospital ("Elmore Hospital") is an Alabama Limited Liability Company with its principal place of business in Elmore County, Alabama. Elmore Hospital is and at all relevant times was a Limited Liability Company organized and operating in Alabama and the United States. Elmore Hospital purchased directly from Philips RS North America LLC, f/k/a Respironics, Inc. two Philips OmniLab Advanced + continuous ventilators for use in Alabama. Elmore Hospital was unaware of the Defect at the time of the purchase, and only became aware of the Defect after it learned that its devices were included in the Recall. Had Elmore Hospital been aware of the Defect in its Omnilab Advanced + devices, it would not have purchased them.

Elmore Hospital seeks full reimbursement of all costs and damages associated with purchasing the Recalled Devices and all costs and damages associated with the Recall.

28. Plaintiff Gail Gilliard-Gunter (“Gilliard-Gunter”) is and at all relevant times was a citizen of the United States and has lived in Louisiana and Arizona since acquiring the Recalled Devices. Plaintiff paid for a Philips DreamStation CPAP on or about 2017, while residing in Louisiana, and a Philips DreamStation BiPAP on or about January 2020, while residing in Arizona. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have acquired the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$1,200.

29. Plaintiff Jeffrey Groudan (“Groudan”) is and at all relevant times was a citizen of Arizona and the United States. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff paid for a Philips DreamStation Auto CPAP on or about November 2020, in Arizona. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall.

While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

30. Plaintiff Russell Autry ("Autry") is and at all relevant times was a citizen of Arkansas and the United States. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about December 2019, in Arkansas. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$30.

31. Plaintiff Paul Bailey ("Bailey") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation Auto BiPAP on or about October 2018, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,100.

32. Plaintiff Michael Bastasch (“Bastasch”) is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips REMStar Auto, BLUETOOTH, Dom on or about August 2015, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,100.

33. Plaintiff Mary Campbell (“Campbell”) is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation on or about 2018 or 2019, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall.

While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$800.

34. Plaintiff Matthew Krantz ("Krantz") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation on or about the August of 2018, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

35. Plaintiff Don Luenebrink ("Luenebrink") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about September 2019, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs



associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$80.

36. Plaintiff Douglas Mest ("Mest") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP HumCell DOM on or about October 2016, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,000.

37. Plaintiff Lisa Mitrovich ("Mitrovich") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation on or about February 2019, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-

pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

38. Plaintiff Patrick Nielson ("Nielson") is and at all relevant times was a citizen of the United States and has lived in Oregon and California since acquiring the Recalled Devices. Plaintiff paid for a Philips Respironics PR System One REMstar Pro on or about March 2014, in California, and paid for another Philips Respironics PR System One REMstar Pro on or about May 2016, in Oregon. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$300.

39. Plaintiff Jimy Ruiz ("Ruiz") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation ProHumCell CPAP on or about October 2018, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall.

While some of Plaintiff's costs may have been paid for by insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$140.

40. Plaintiff Robert Waybright ("Waybright") is and at all relevant times was a citizen of California and the United States. Plaintiff paid for a Philips DreamStation on or about March 2016, in California. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$30.

41. Plaintiff Kenneth Archuleta ("Archuleta") is and at all relevant times was a citizen of Colorado and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about April 2020, in Colorado. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

42. Plaintiff Sylvia McDaniel ("McDaniel") is and at all relevant times was a citizen of Colorado and the United States. Plaintiff paid for a Philips DreamStation on or about August 2019, in Colorado. The Recalled Device was purchased for personal, family, or household

purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

43. Plaintiff Natalie Gottlieb ("Gottlieb") is and at all relevant times was a citizen of Connecticut and the United States. Plaintiff paid for a Philips DreamStation on or about March 2020, in Connecticut. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,200.

44. Plaintiff Paul Rohan ("Rohan") is and at all relevant times was a citizen of Connecticut and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about May 2019, in Connecticut. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device,

Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$800.

45. Plaintiff Jose Toscano ("Toscano") is and at all relevant times was a citizen of Connecticut and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about November 2016, and a second Philips DreamStation Auto CPAP on or about November 2020, in Connecticut. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$500.

46. Plaintiff Anthony George ("George") is and at all relevant times was a citizen of Delaware and the United States. Plaintiff paid for a Philips DreamStation BiPAP on or about August 2019, in Delaware. The Recalled Device was purchased for personal, family, or

household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,150.

47. Plaintiff Bert Gibbons ("Gibbons") is and at all relevant times was a citizen of Delaware and the United States. Plaintiff paid for two Philips Respironics SystemOne devices on or about January 13, 2015, and January 5, 2019, in Delaware. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$1,550.

48. Plaintiff Donald Boyd ("Boyd") is and at all relevant times was a citizen of Florida and the United States. Plaintiff paid for a Philips REMstar on or about November 2014, in Florida, and Plaintiff paid for a Philips DreamStation on or about October 2019, in Florida. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's devices were included in the

Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices and replacement device are at least \$150.

49. Plaintiff Kenneth Dzierzanowski ("Dzierzanowski") is and at all relevant times was a citizen of the United States. Plaintiff paid for a Philips DreamStation Auto CPAP HumHT DOM in September 2020, while residing in Maryland. In 2022, Plaintiff moved to Florida. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$500.

50. Plaintiff Tara Fields ("Fields") is and at all relevant times was a citizen of Florida and the United States. Plaintiff paid for a Philips REMStar CPAP in or around July 2020 in Florida. She then paid for a Philips DreamStation CPAP on or about September 2020. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defects in Plaintiff's devices, Plaintiff would not have

paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$150.

51. Plaintiff Dennis Morris ("Morris") is and at all relevant times was a citizen of Florida and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about November 2018, in Florida. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and a replacement ResMed device are at least \$1,000.

52. Plaintiff Glenn Paraday ("Paraday") is and at all relevant times was a citizen of Florida and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about September 2019, in Florida. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a



replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and a replacement device are at least \$900.

53. Plaintiff Barbara Smith ("Smith") is and at all relevant times was a citizen of Florida and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP in the Spring of 2017, and a second DreamStation Auto CPAP in April 2018, in Florida. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$30.

54. Plaintiff Rudolph J. Childre Jr. ("Childre") is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about March 2017, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was

not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and a replacement device are at least \$500.

55. Plaintiff Eric Michael Davis ("Davis") is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips REMStar System One CPAP on or about December 2015, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$900.

56. Plaintiff Roy Fultz ("Fultz") is and at all relevant times was a citizen of the United States and has lived in Ohio and Georgia since acquiring the Recalled Device. Plaintiff paid for a Philips Respironics SystemOne REMstar Q-Series on or about 2015, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's

costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

57. Plaintiff Dephine Lewis ("Lewis") is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips Respironics DreamStation 1 in or around May 2019, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$150.

58. Plaintiff Jared Luke ("Luke") is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP in or around June 2021, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,300.

59. Plaintiff John Mercure (“Mercure”) is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP in or around October 2020, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$300.

60. Plaintiff Richard Sizemore (“Sizemore”) is and at all relevant times was a citizen of Georgia and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about May 2017, in Georgia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$700.

61. Plaintiff Chris Brown (“Brown”) is and at all relevant times was a citizen Hawaii and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about October

2017, in of Hawaii. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$200.

62. Plaintiff Chad Savoure ("Savoure") is and at all relevant times was a citizen of Idaho and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about February 2021, in Idaho. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$17.

63. Plaintiff Danny Baran (“Baran”) is and at all relevant times was a citizen of Illinois and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP in or about February 2019, in Illinois. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$500.

64. Plaintiff Shannon Brooks (“Brooks”) is and at all relevant times was a citizen of Illinois and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about March 2021, in Illinois. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,000.

65. Plaintiff Debbie Rootberg (“Rootberg”) is and at all relevant times was a citizen of Illinois and the United States. Plaintiff paid for a Philips REMstar Pro on or about June 2012, in Illinois. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$100.

66. Plaintiff Diane Anderson is and at all relevant times was a citizen of Indiana and the United States. Plaintiff paid for a Philips Respironics DreamStation 1 on or about December 2019, in Indiana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

67. Plaintiff Steven Clark (“Clark”) is and at all relevant times was a citizen of Indiana and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about December 2020, in Indiana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$40.

68. Plaintiff Steve Abarr (“Abarr”) is and at all relevant times was a citizen of Iowa and the United States. Plaintiff paid for a Philips SystemOne on or about March 2015 and a Philips DreamStation Auto BiPAP on or about December 2019, in Iowa. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$1,200.

69. Plaintiff Asherdee Diamond (“Diamond”) is and at all relevant times was a citizen of Iowa and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about



2016, and a Philips REMstar A-Flex on or about 2019, in Iowa. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$300.

70. Plaintiff Jeff Wilson ("Wilson") is and at all relevant times was a citizen of Iowa and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about March 2020, in Iowa. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$1,500.

71. Plaintiff Sharon Cathers ("Cathers") is and at all relevant times was a citizen of Kansas and the United States. Plaintiff paid for a Philips DreamStation on or about January 2021, in Kansas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device

was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,000.

72. Plaintiff John Ratliff ("Ratliff") is and at all relevant times was a citizen of Kentucky and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about 2019, in Kentucky. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

73. Plaintiff Paul Baudoin ("Baudoin") is and at all relevant times was a citizen of Louisiana and the United States. Plaintiff paid for a Philips REMstar Pro 60 on or about December 2017, in Louisiana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-

pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$350.

74. Plaintiff John Couch ("Couch") is and at all relevant times was a citizen of Louisiana and the United States. Plaintiff paid for a Philips Dream Station on or about 2015, in Louisiana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and any replacement device are at least \$900.

75. Plaintiff Susan Martin is and at all relevant times was a citizen of Louisiana and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about June 2020, in Louisiana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$500.

76. Plaintiff Ronald Romas (“Romas”) is and at all relevant times was a citizen of Louisiana and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP in Louisiana on or about July 2018. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$40.

77. Plaintiff Julie Barrett is and at all relevant times was a citizen of the United States and has lived in Maine and Oregon since paying for a Recalled Device. While residing in Maine, Plaintiff paid for a Philips CPAP Auto – Dream/DreamStation Auto Pap with Humidifier on or about July 2018, from a provider in New Hampshire. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$400.

78. Plaintiff Peter Barrett is and at all relevant times was a citizen of the United States and has lived in Maine and Oregon since paying for a Recalled Device. While residing in Maine, Plaintiff paid for a Philips CPAP Auto – Dream/DreamStation Auto Pap with Humidifier on or

about July 2018, from a provider in New Hampshire. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$400.

79. Plaintiff Doris Margoles ("Margoles") is and at all relevant times was a citizen of the United States and has resided in Maine and North Carolina since acquiring the Recalled Device. Plaintiff paid for a Philips DreamStation Auto CPAP on or about October 2017, in Maine. Plaintiff now lives in North Carolina. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

80. Plaintiff Ryan Schwartz ("Schwartz") is and at all relevant times was a citizen of Maine and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP HumHTCell

Dom on or about January 19, 2018, in Maine. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

81. Plaintiff Pete Bellotti ("Bellotti") is and at all relevant times was a citizen of Massachusetts and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about September 2017, in Massachusetts. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$200.

82. Plaintiff Daniel F. Conley ("Conley") is and at all relevant times was a citizen of Massachusetts and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about April 2020, in Massachusetts. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's

device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

83. Plaintiff Marc Whaley ("Whaley") is and at all relevant times was a citizen of Massachusetts and the United States. Plaintiff paid for a Philips DreamStation in or around 2019, in Massachusetts. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,400.

84. Plaintiff William Wilks ("Wilks") is and at all relevant times was a citizen of Michigan and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about December 2020, in Michigan. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-

pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

85. Plaintiff Prinna Boudreau ("Boudreau") is and at all relevant times was a citizen of Minnesota and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about 2011, and a Philips System One BiPAP Auto on or about 2019 or 2020, in Minnesota. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$850.

86. Plaintiff Robert Bruce Mold ("Mold") is and at all relevant times was a citizen of Minnesota and the United States. Plaintiff paid for a Philips DreamStation BiPAP on or about December 2017, in Minnesota. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall.



While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$1,000.

87. Plaintiff Mary Godeaux ("Godeaux") is and at all relevant times was a citizen of Mississippi and the United States. Plaintiff paid for a Philips A-Series BiPAP Auto on or about May 2016, in Mississippi. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

88. Plaintiff James Jefferson Rankin ("Rankin") is and at all relevant times was a citizen of Mississippi and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about May 2020, in Mississippi. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$400.

89. Plaintiff Grady Tucker, Jr. ("Tucker") is and at all relevant times was a citizen of Mississippi and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP DOM on or about 2017, and a Philips DreamStation Go Auto CPAP on or about June 2, 2021, in

Mississippi. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$500.

90. Plaintiff John Young ("Young") is and at all relevant times was a citizen of Missouri and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about January 2021, in Missouri. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,600.

91. Plaintiff Danny David ("David") is and at all relevant times was a citizen of Montana and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about January 2021, in Montana. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's

device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$500.

92. Plaintiff Elizabeth Lemus ("Lemus") and at all relevant times was a citizen of Nevada and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about September 2017, in Nevada. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$70.

93. Plaintiff Elaine Lizotte ("Lizotte") is and at all relevant times was a citizen of New Hampshire and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about June 2019, in New Hampshire. The Recalled Device was purchased for personal,

family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$400.

94. Plaintiff William Vlahos ("Vlahos") is and at all relevant times was a citizen of New Hampshire and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about October 2018, from a provider in Massachusetts. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$400.

95. Plaintiff Susanne Dennis ("Dennis") is and at all relevant times was a citizen of New Jersey and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or

about November 2018, in New Jersey. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,500.

96. Plaintiff Joseph Ryan ("Ryan") is and at all relevant times was a citizen of New Jersey and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about July 2018, in New Jersey. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$750.

97. Plaintiff Aaron Taylor (“Taylor”) is and at all relevant times was a citizen of New Jersey and the United States. Plaintiff paid for a Philips DreamStation Respiroics REMstar Pro C-Flex+ System One in or around 2007 or 2008 and paid for a DreamStation CPAP Pro Hum Cell DOM in or around 2015, in New Jersey. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$900

98. Plaintiff Mark Bossey (“Bossey”) is and at all relevant times was a citizen of New York and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about November 2019, in New York. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$750.

99. Plaintiff Bruce Ginsberg (“Ginsberg”) is and at all relevant times was a citizen of New York and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about 2018, in New York. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

100. Plaintiff Carl Gold (“Gold”) is and at all relevant times was a citizen of the United States. At relevant times, Gold lived in New York and New Jersey. Plaintiff paid for a Philips DreamStation Auto CPAP on or about August 2020, in New York. He currently lives in New Jersey. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated

with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

101. Plaintiff Jeffrey Bartalo ("Bartalo") is and at all relevant times was a citizen of North Carolina and the United States. Plaintiff paid for a Philips DreamStation on or about December 2019, in North Carolina. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$800.

102. Plaintiff Patricia Flick ("Flick") is and at all relevant times was a citizen of Ohio and the United States. Plaintiff paid for a Philips Respironics CPAP machine on or about October 2014, in Ohio. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

103. Plaintiff Jack Giordano ("Giordano") is and at all relevant times was a citizen of Ohio and the United States. Plaintiff paid for a Philips DreamStation on or about April 2016, in



Ohio. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$100.

104. Plaintiff Rachel Hock ("Hock") is and at all relevant times was a citizen of Ohio and the United States. Plaintiff paid for a Philips System One REMstar 50 Series on or about 2014, and a Philips DreamStation Auto CPAP on or about November 2018, in Ohio. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$100.

105. Plaintiff Vincent Stefanini ("Stefanini") is and at all relevant times was a citizen of Ohio and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about November 2019, in Ohio. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device

was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

106. Plaintiff Matthew Ward ("Ward") was at all relevant times a citizen of Ohio and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about December 2016, in Ohio. Plaintiff moved to Florida in May 2022. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

107. Plaintiff Jason Mcelyea ("Mcelyea") is and at all relevant times was a citizen of Oklahoma and the United States. Plaintiff paid for two Philips DreamStation Auto CPAPs on or about November 2020, in Oklahoma. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full

reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$1,400.

108. Plaintiff John Masington ("Masington") is and at all relevant times was a citizen of Pennsylvania and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP Hum DOM on or about December 19, 2016, and a second Philips DreamStation on or about April 24, 2017, in Pennsylvania. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$400.

109. Plaintiff Marilyn Sweeney ("Sweeney") is and at all relevant times was a citizen of Pennsylvania and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP HTWifi DOM on or about February 1, 2019, and a Philips DreamStation Go Auto CPAP on or about February 12, 2019, in Pennsylvania. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device,

Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$800.

110. Plaintiffs Antonio Perez Bonano ("Bonano") is and at all relevant times was a citizen of Puerto Rico and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about April 2019, in Puerto Rico. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

111. Plaintiff Diane Lamontagne ("Lamontagne") is and at all relevant times was a citizen of Rhode Island and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about March 2016, in Rhode Island. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through

insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

112. Plaintiff Mark Weiner ("Weiner") is and at all relevant times was a citizen of Rhode Island and the United States. While residing in Rhode Island, Plaintiff paid for a Philips DreamStation from a provider located in Massachusetts. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

113. Plaintiff William Anderson is and at all relevant times was a citizen of South Carolina and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about June 2018, in South Carolina. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

114. Plaintiff Adam Cote (“Cote”) is and at all relevant times was a citizen of Tennessee and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about October 2019, in Tennessee. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$500.

115. Plaintiff Murray Craig (“Craig”) is and at all relevant times was a citizen of Tennessee and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about October 2019, in Tennessee. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

116. Plaintiff Sarah Claunch (“Claunch”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about September 2018, in Texas. The Recalled Device was purchased for personal, family, or

household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$600.

117. Plaintiff Ronald Cline ("Cline") is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about December 2020, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for by insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$1,550.

118. Plaintiff Raul Deleon ("Deleon") is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP in October 2019, and a DreamStation Go in January 2020, in Texas. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through

insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$700

119. Plaintiff Sarah Lowney ("Lowney") is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about April 2020, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$400.

120. Plaintiff Sabrina Malone ("Malone") is and at all relevant times was a citizen of the United States. At relevant times, she has lived in Texas and New Hampshire. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP on or about January 2018, in Texas, and since acquiring the device, she has lived in New Hampshire. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$50.



121. Plaintiff Paul Panzera (“Panzera”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about August 2018, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$300.

122. Plaintiff Roland Rendon (“Rendon”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about November 2019, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$20.

123. Plaintiff Michael Tobin (“Tobin”) is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP HumTCell on

or about February 2020, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$100.

124. Plaintiff Ronald Turner ("Turner") is and at all relevant times was a citizen of Texas and the United States. Plaintiff paid for a Philips REMStar Auto CPAP on or about October 2013, in Texas. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for by insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$250.

125. Plaintiff David Martin is and at all relevant times was a citizen of Vermont and the United States. Plaintiff paid for a Philips REMstar Auto BiPAP on or about 2011, and a Philips DreamStation Auto BiPAP on or about 2017, in Vermont. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff's devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective

breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$1,200.

126. Plaintiff Elizabeth Heilman ("Heilman") is and at all relevant times was a citizen of Virginia and the United States. Plaintiff paid for a Philips DreamStation on or about August 2018, in Virginia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

127. Plaintiff Penny Hudson ("Hudson") is and at all relevant times was a citizen of the Virginia and the United States. Plaintiff paid for a Philips DreamStation on or about December 2019, in Virginia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff's device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff's device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff's costs may have been paid for through insurance, Plaintiff's out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

128. Plaintiff Beth Rodgers (“Rodgers”) is and at all relevant times was a citizen of the United States and has lived in New Mexico and Virginia since acquiring a Recalled Device. Plaintiff paid for a Philips SystemOne on or about 2013, while living in New Mexico, and a Philips DreamStation in or about June 2019, while living in Virginia. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have paid for the devices. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Devices and the replacement device are at least \$800.

129. Plaintiff Cameron Rose (“Rose”) is and at all relevant times was a citizen of Virginia and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about April 2018, in Virginia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-

pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$100.

130. Plaintiff Jose Lopez (“Lopez”) is and at all relevant times was a citizen of Washington and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about December 2018 or January 2019, in Washington. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$900.

131. Plaintiff Robert Peebles (“Peebles”) is and at all relevant times was a citizen of Washington and the United States. Plaintiff paid for a Philips DreamStation on or about October 2020, in Washington. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$300.

132. Plaintiff David Bays (“Bays”) is and at all relevant times was a citizen of West Virginia and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP on or about January 2020, in West Virginia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$150.

133. Plaintiff Brent Hamlin (“Hamlin”) is and at all relevant times was a citizen of West Virginia and the United States. Plaintiff paid for a Philips Respironics DreamStation Auto CPAP in or about December 2019, in West Virginia. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device are at least \$200.

134. Plaintiff Donald Rucker (“Rucker”) is and at all relevant times was a citizen of West Virginia and the United States. Plaintiff paid for a Philips DreamStation CPAP on or about September 2019, and then acquired a second DreamStation in 2020, both in West Virginia. The Recalled Devices were purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the times of acquisition, and Plaintiff’s devices were included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s devices, Plaintiff would not have paid for the devices. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Devices and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Devices are at least \$30.

135. Plaintiff Robert Matters (“Matters”) is and at all relevant times was a citizen of Wisconsin and the United States. Plaintiff paid for a Philips DreamStation Auto CPAP in or around November 2019, while residing in Wisconsin. The Recalled Device was purchased for personal, family, or household purposes. Plaintiff was unaware of the Defect at the time of acquisition, and Plaintiff’s device was included in the Recall. Had Plaintiff been aware of the Defect in Plaintiff’s device, Plaintiff would not have paid for the device. As a result of the Recall and because Plaintiff was not immediately provided by Philips with a non-defective breathing device, Plaintiff paid for a replacement device not manufactured by Philips. Plaintiff seeks full reimbursement of all out-of-pocket costs associated with acquiring the Recalled Device and costs associated with the Recall. While some of Plaintiff’s costs may have been paid for through insurance, Plaintiff’s out-of-pocket costs related to the acquisition of the Recalled Device and the replacement device are at least \$1,000.

136. Plaintiff ASEA/AFSCME Local 52 Health Benefits Trust (the “ASEA Health Trust”) is a third-party payor (“TPP”).<sup>18</sup> The ASEA Health Trust is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. The ASEA Health Trust provides healthcare benefits to plan participants and their eligible family members consisting of permanent and long-term nonpermanent employees of the State of Alaska General Government Unit covered by a collective bargaining agreement between the State of Alaska and the ASEA Health Trust. The ASEA Health Trust is organized under federal law and provides benefits to Alaska state employees. The ASEA Health Trust paid thousands of dollars towards the cost of Recalled Devices for the personal use of its plan participants. At the time the ASEA Health Trust paid a portion of the cost of Recalled Devices, it was unaware of the Defect because Defendants intentionally withheld information about the Defect. Had Defendants timely and appropriately disclosed the Defect, that information would have been accessible to prescribing physicians and the general public, and physicians would not have prescribed the Recalled Devices. Had Defendants timely and appropriately disclosed the Defect, the ASEA Health Trust would not have paid for Recalled Devices that were worthless because of the Defect. The ASEA Health Trust seeks full reimbursement of all costs associated with acquiring the Recalled Devices for its plan participants and for the costs of replacing the Recalled Devices.

137. Plaintiff Ohio Carpenters’ Health Fund (“Ohio Carpenters”) is a TPP. Ohio Carpenters is located in Troy, Michigan. Ohio Carpenters is a tax-exempt IRC Section 501(c)(9) Voluntary Employee Benefit Association. Ohio Carpenters is also a multiemployer, collectively

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<sup>18</sup> The term “third-party payor” or “TPP” refers to private health insurance companies, third-party administrators, health maintenance organizations, health and welfare plans that make payments for health benefits from their own funds, and other health benefit providers and entities with self-funded plans that contract with a health insurer or administrator to administer their health benefits.



bargained trust fund established in accordance with Labor Management Relations Act § 302(c)(5), 29 U.S.C. § 186(c)(5), for the purpose of providing benefits for employees and their beneficiaries. Ohio Carpenters provides healthcare benefits to Participants and their eligible dependents (collectively, Beneficiaries). The Ohio Carpenters' Plan document provides the Ohio Carpenters the right to pursue claims that the Participants and Beneficiaries have against third parties. From at least 2017 through the date of the Recall, Ohio Carpenters, in whole or part, paid for or reimbursed payment for tens of thousands of Recalled Devices and expended at least hundreds of thousands of dollars on Recalled Devices on behalf of its insured Beneficiaries located in at least the following states: Alaska, Arizona, Florida, Indiana, Kentucky, Michigan, New Jersey, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, and West Virginia. The Recalled Devices were purchased for personal use. Ohio Carpenters is ultimately at risk and responsible for reimbursing or paying for Beneficiaries' purchases of medically necessary medical devices, such as the Recalled Devices. Ohio Carpenters was unaware of the Defect at the time of the purchases of the Recalled Devices. Had Ohio Carpenters been aware of the Defect in devices they purchased, Ohio Carpenters would not have paid for the devices for its Beneficiaries. As a result of the Recall and because Ohio Carpenters' Beneficiaries were not immediately provided by Philips with non-defective breathing devices, Ohio Carpenters also paid for replacement devices not manufactured by Philips. Ohio Carpenters seeks full reimbursement of all out-of-pocket costs associated with paying or reimbursing for the Recalled Devices for itself and its Beneficiaries and all costs associated with the Recall including costs for the replacement of any Recalled Devices.

138. Plaintiffs MSP Recovery Claims Series, LLC ("MSPRC"); MSPA Claims 1, LLC ("MSPA"); MAO-MSO Recovery II, LLC, Series PMPI ("MAO-MSO"); MSP Recovery Claims

Series 44, LLC (“Series 44”); MSP Recovery Claims PROV, Series LLC (“Claims PROV”); and MSP Recovery Claims CAID, Series LLC (“Claims CAID”) (collectively referred to as “MSP”) have obtained irrevocable assignments of any and all rights to recover reimbursement or payment from Defendants. MSP’s Assignors (the “Assignors”) provide health insurance coverage, pursuant to Medicare Part C and Part D, Medicaid, or commercial contracts for insurance, to persons that subscribe to their plans (the “Enrollees”).

139. MSPRC is a Delaware series limited liability company with its principal place of business in Coral Gables, Florida. MSPRC’s limited liability company agreement provides for the establishment of one or more designated Series. MSPRC has established various designated series pursuant to Delaware law to maintain various claims recovery assignments separate from other Company assets, and to account for and associate certain assets with certain particular series. Pursuant to MSPRC’s limited liability agreement, all designated series form a part of MSPRC. MSPRC may receive assignments in the name of MSPRC and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, MSPRC will maintain the right to sue on behalf of each series and pursue any and all rights, benefits, and causes of action arising from assignments to a series. Any claim or suit may be brought by MSPRC in its own name or it may elect to bring suit in the name of its designated series. MSPRC’s limited liability agreement provides that any rights and benefits arising from assignments to any of its series shall belong to MSPRC.

140. As an example, on June 26, 2019, one of MSP’s Assignors, AvMed, Inc. (“AvMed”), entered into a Claims Purchase Agreement & Assignment with Series 17-03-615, a designated series of MSPRC, whereby it irrevocably assigned all rights to recover payments

made on behalf of its Enrollees (the “AvMed Assignment”). The AvMed Assignment expressly provides, in pertinent part:

Assignor irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its designated series, successors and assigns, any and all of Assignor's right, title, ownership and interest in and to (i) all Claims existing on the date hereof, whether based in contract, tort or statutory right, and all related recovery rights arising from and related to the claims data transferred to MSP Recovery (or its affiliates or service providers, including [MSP Recovery]), and (ii) any and all causes of action, claims and demands of any nature whatsoever relating to payments for health care services provided to Assignor's members and enrollees, and legal or equitable rights (including, but not limited to, subrogation) to pursue and/or recover monies related to the Claims that Assignor had, may have had, or has asserted against any party in connection with the Claims; and (iii) all causes of action, claims, rights and demands of any nature whatsoever, legal or equitable, against primary payers, Responsible Parties and/or third parties that may be liable to Assignor arising from or relating to the Claims, including claims under consumer protection statutes and laws (all of the items set forth in (i)-(iii), the “Assigned Claims”) . . . . The assignment of the Assigned Claims set forth herein is irrevocable and absolute.

141. MSPA is a limited liability company that is duly organized, validly existing, and in good standing under the laws of Florida, with its principal place of business in Coral Gables, Florida.

142. MAO-MSO, a segregated series of MAO-MSO Recovery II, LLC, is a Delaware series limited liability company that is duly organized, validly existing, and in good standing under the laws of Delaware, with its principal place of business in Cresskill, New Jersey.

143. Series 44 is a duly organized and existing Delaware series limited liability company with its principal place of business in Coral Gables, Florida. Series 44's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and to

account for and associate certain assets with certain particular series. Series 44 has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Series 44. Series 44 may receive assignments in the name of Series 44 and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Series 44 and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Series 44 retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series.

144. Claims PROV is a duly organized and existing Delaware series limited liability company with its principal place of business in Coral Gables, Florida. Claims PROV's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims PROV established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series. Claims PROV has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims PROV. Claims PROV may receive assignments in the name of Claims PROV and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event,

Claims PROV and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims PROV retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series.

145. Claims CAID is a duly organized and existing Delaware series limited liability company with its principal place of business in Coral Gables, Florida. Claims CAID's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims CAID established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series. Claims CAID has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims Prov. Claims CAID may receive assignments in the name of Claims CAID and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims CAID and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims CAID retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series.

146. Philips is one of the largest manufacturers of CPAP and BiPAP machines in the United States, accounting for approximately 30% of all CPAP and BiPAP machines sold. MSP's Assignors<sup>19</sup> made payments for or are otherwise financially responsible for tens of thousands of CPAP or BiPAP machines, and those Assignors or the downstream entities that provided the health services are located in the following states: California, Connecticut, Florida, Illinois, Massachusetts, Michigan, New York, Ohio, Puerto Rico, Rhode Island, Texas, and Wisconsin.

147. The Enrollees of MSP's Assignors also generally make co-payments for medical devices, such as Philips' CPAP and BiPAP machines, and, on information and belief, likely also made partial co-payments for the Recalled Devices.

148. As an example, below are some payments or reimbursements made by AvMed, one of MSP's Assignors, for the lease or purchase of Philips' defective DreamStation or REMstar SE Auto Recalled Devices:

<b>Patient</b>	<b>Defendant</b>	<b>Model</b>	<b>Assignor</b>
D.W.	Philips	dsx500h11	AvMed
G.M.	Philips	dsx500h11	AvMed
P.F.	Philips	dsx200h11	AvMed
C.T.	Philips	dsx200h11	AvMed
R.M.	Philips	dsx200h11	AvMed
Z.M.	Philips	ds220hs	AvMed
E.T.	Philips	dsx200h11	AvMed

149. Those Recalled Devices were purchased for personal use, and in total, AvMed paid or reimbursed payment for over \$950,000 for the defective Recalled Devices.

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<sup>19</sup> Although MSP is not a TPP, MSPRC, MSPA, MAO-MSO, Series 44, Claims PROV, and Claims CAID are assignees of TPPs and thereby stand in their assignors' shoes and have standing to represent TPPs.

150. MSP's Assignors were unaware of the Defect at the time of the purchases of the Recalled Devices. Had MSP's Assignors been aware of the Defect in the Recalled Devices they purchased, leased, or reimbursed payment for, they would not have paid for or reimbursed payment for the devices for their Enrollees. Once the Recall was issued, MSP's Assignors' Enrollees were not immediately provided by Philips with non-defective breathing devices.

## **B. DEFENDANTS**

151. Defendant Royal Philips is a Dutch multinational publicly traded company having its principal executive offices at Philips Center, Amstelplein 2, 1096 BC Amsterdam, The Netherlands. Royal Philips is the ultimate parent company of the Philips Group of healthcare technology businesses including Connected Care businesses focusing on Sleep & Respiratory Care.<sup>20</sup> "The Company, which started as a limited partnership with the name Philips & Co in Eindhoven, the Netherlands, in 1891, was converted into the company with limited liability N.V. Philips' Gloeilampenfabrieken on September 11, 1912. The Company's name was changed to Philips Electronics N.V. on May 6, 1994, and then to Koninklijke Philips Electronics N.V. on April 1, 1998, and [finally] to Koninklijke Philips N.V. on May 15, 2013."<sup>21</sup> Royal Philips' shares have been listed on the Amsterdam stock exchange since 1912, have been traded in the

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<sup>20</sup> Royal Philips Press Release, Philips realigns the composition of its reporting segments (Jan. 10, 2019), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2019/20190110-philips-realigns-the-composition-of-its-reporting-segments.html> (last accessed Oct. 8, 2022) (attached hereto as Exhibit "137").

<sup>21</sup> Royal Philips 2017 Annual Report (attached hereto as Exhibit "12"), at 84. Note all quarterly and annual reports and SEC 20-F filings from 2009 to the present can be found at this link, under the "All Results" tab: <https://www.results.philips.com/publications/ar21> (last accessed Oct. 3, 2022).

United States since 1962, and have been listed on the New York Stock exchange since 1987.<sup>22</sup> Royal Philips holds directly or indirectly 100% of its subsidiaries, Philips NA, Philips USA, Philips RS Holding, and Philips RS.<sup>23</sup> As such, Royal Philips controls Philips NA and Philips RS with respect to the manufacturing, selling, distributing, and supplying of the Recalled Devices.<sup>24</sup>

152. Defendant Philips NA is a Delaware company that was incorporated on August 6, 1987,<sup>25</sup> having its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA was “formerly known as Philips Electronics North America

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<sup>22</sup> *Id.*; see also Royal Philips 2021 Annual Report, available for download at <https://www.results.philips.com/publications/ar21> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “13”), at 117.

<sup>23</sup> Royal Philips 2021 SEC Form 20-F filing, Exhibit 8, List of Subsidiaries, available at: <https://www.sec.gov/Archives/edgar/data/313216/000031321622000008/phg-exhibit8.htm> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “14”). In its 2019 SEC Form 20-F filing, Exhibit 8, Royal Philips also lists Respireonics, Inc. as a wholly-owned subsidiary (attached hereto as Exhibit “15”). However, Respireonics, Inc. is no longer listed as a subsidiary on Royal Philips 2020 SEC Form 20-F filing, Exhibit 8, available at: <https://www.sec.gov/ix?doc=/Archives/edgar/data/0000313216/000031321621000008/phg-20201231.htm> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “16”); rather, Royal Philips lists Philips RS North America LLC as a subsidiary. *Id.*

<sup>24</sup> See Royal Philips 2020 SEC Form 20-F filing, Exhibit 8 (Exhibit “16” hereto).

<sup>25</sup> State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips North America LLC (attached hereto as Exhibit “17”).



Corporation.”<sup>26</sup> Philips NA is a wholly-owned subsidiary of Royal Philips, managed by Philips USA.<sup>27</sup>

153. Defendant Philips USA is a Delaware corporation that was incorporated on July 18, 1995,<sup>28</sup> having its principal place of business at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips USA is a holding company that is 100% owned, directly or indirectly, by Royal Philips. Philips USA manages the operations of Royal Philips’ various lines of business including Philips RS Holding and through it, Philips RS.<sup>29</sup> Philips USA is also the member/manager of Philips NA.<sup>30</sup>

154. Defendant Philips RS is a Delaware company that was incorporated on February 22, 1984,<sup>31</sup> having its principal place of business at 6501 Living Place, Pittsburgh, Pennsylvania 15206. Philips RS is 100% owned by Philips RS Holding, which in turn, is 100% owned by

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<sup>26</sup> See Complaint for Patent Infringement in *Koninklijke Philips N.V., et al. v. Mediatek, Inc., et al.*, No. 1:20-cv-01246-UNA, ECF No. 1, (D. Del. Sept. 17, 2020) (attached hereto as Exhibit “18”). “Philips Electronics North America Corporation” is listed as a subsidiary of Royal Philips as of its 2016 Annual Report, Exhibit 8, List of Subsidiaries (attached hereto as Exhibit “19”). “Philips North America LLC” is not listed therein. *Id.* However, “Philips North America LLC” is listed as a subsidiary of Royal Philips on the 2017 SEC 20-F filing, Exhibit 8, List of Subsidiaries, available at: <https://www.sec.gov/Archives/edgar/data/313216/000119312517050359/d330553d20f.htm> (last accessed Oct. 4, 2022) (attached hereto as Exhibit “20”).

<sup>27</sup> Corporate Disclosure Statement in *Newsome, Jr., et al. v. Philips North America LLC, Koninklijke Philips N.V., Philips RS North America LLC, Respireonics, Inc., et al.*, 4:22-cv-04101-HSG (N.D. Cal. July 13, 2022), ECF No. 2 (“Newsome Corp. Discl. Stmt.”) (attached hereto as Exhibit “21”).

<sup>28</sup> State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips Holding USA Inc. (attached hereto as Exhibit “22”).

<sup>29</sup> Newsome Corp. Discl. Stmt. (Exhibit “21” hereto).

<sup>30</sup> *Id.*

<sup>31</sup> State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips RS North America LLC (attached hereto as Exhibit “23”).

Philips USA.<sup>32</sup> Philips RS formerly operated under the business name Respiroics, Inc. (“Respiroics”). Royal Philips acquired Respiroics in 2008,<sup>33</sup> creating “Philips Respiroics.”<sup>34</sup> However, “Philips Respiroics is a fictitious name that is 100% owned by Philips RS [N]orth America LLC.”<sup>35</sup> In October 2020, shortly before the Recall, Respiroics, Inc. was newly registered under the name Philips RS North America, LLC.<sup>36</sup>

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<sup>32</sup> See Newsome Corp. Discl. Stmt. (Exhibit “21” hereto); *see also, e.g.*, State of Mississippi, Secretary of State, certificate for Philips RS North America LLC (Respiroics, Inc.), which lists that it is a “Member” of Philips RS North America Holding Corporation. This certificate also states an “intent to dissolve” with an effective date of “04/05/2017” (attached hereto as Exhibit “24”).

<sup>33</sup> Philips announces completion of tender offer to acquire Respiroics, WebWire (Mar. 14, 2008), <https://www.webwire.com/ViewPressRel.asp?aId=61199> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “25”).

<sup>34</sup> See *History of BiPAP – Respiroics and Philips Respiroics*, *cpap.com*, last updated (Dec. 9, 2021), <https://www.cpap.com/blog/history-bipap-respiroics-philips/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “26”); *see also* Philips in \$5 billion Respiroics deal, Reuters (Dec. 21, 2007), <https://www.reuters.com/article/us-philips/philips-in-5-billion-respiroics-deal-idUSL2131786820071221> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “27”); *see also* Philips makes \$5.1B public offer to acquire Respiroics, ReliablePlant (undated), [https://www.reliableplant.com/Read/9713/philips-makes-\\$51b-public-offer-to-acquire-respiroics](https://www.reliableplant.com/Read/9713/philips-makes-$51b-public-offer-to-acquire-respiroics) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “28”).

<sup>35</sup> Newsome Corp. Discl. Stmt. (Exhibit “21” hereto). Yet, Philips Respiroics has a dedicated webpage which states, “About Philips Respiroics – As a global leader in the sleep and respiratory markets, we’re passionate about providing solutions that lead to healthier patients, practices, and businesses.” *See* <http://www.respiroics.com/Philips> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “29”). Royal Philips holds the copyright on this webpage as of “2004 – 2022” with “[a]ll rights reserved.” *Id.* The webpage has a link to a “Privacy policy” that is titled “Philips Privacy Notice” that states “the controller of your personal data (as well as the controller’s representative in the European Union) is Philips International B.V. *Id.* Philips International B.V. was founded in 1994. *See Bloomberg* profile for Philips International B.V., <https://www.bloomberg.com/profile/company/1071145D:NA> (last accessed Oct. 5, 2022) (attached hereto as Exhibit “141”). Philips International B.V. is a wholly-owned subsidiary of Royal Philips. Royal Philips 2021 SEC Form 20-F filing, Exhibit 8, List of Subsidiaries (Exhibit “14” hereto).

<sup>36</sup> State of Delaware Certificate of Conversion (Nov. 9, 2020) (attached hereto as Exhibit “30”).

155. Defendant Philips RS Holding is a Delaware corporation that was incorporated on October 31, 2020,<sup>37</sup> having its principal place of business at 222 Jacobs Street, Cambridge, Massachusetts 02141, and is wholly owned by Philips USA. Accordingly, Philips RS Holding is a citizen of Massachusetts and Delaware.

156. At all relevant times, each Philips Defendant acted in all aspects as the agent and alter ego of one another, and reference to “Philips” refers to each Philips Defendant individually and collectively.

157. Defendant Polymer Technologies, Inc. (“PolyTech”) is a Delaware corporation with its principal place of business at 420 Corporate Boulevard, Newark, Delaware 19702. PolyTech directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

158. Defendant Polymer Molded Products LLC (“PMP”) is a Delaware corporation with its principal place of business at 10 Easy Street, Bound Brook, NJ 08805. PMP is a molded polyurethane foam manufacturer. PMP directly or through another intermediary provided Philips with the PE-PUR foam that was used in the Recalled Devices.

159. At all relevant times, Defendants PolyTech and PMP acted in all respects as the agent and alter ego of one another, and reference hereinafter to “PolyTech” or the “PolyTech Defendants” refers to Defendants PolyTech and PMP individually and collectively.

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<sup>37</sup> State of Delaware, Dept. of State, Div. of Corporations, Entity Details of Philips RS North America Holding Corporation (attached hereto as Exhibit “31”).

**C. THE GLOBAL PHILIPS ENTERPRISE, INCLUDING ALL PHILIPS ENTITIES NAMED AS DEFENDANTS, OPERATES AS A UNIFIED ENTITY KNOWN SIMPLY AS “PHILIPS.”**

160. Royal Philips controls and oversees all aspects of the Philips businesses around the world, going to great lengths to ensure there is a unity of purpose and vision, consistent execution of company procedures, policies, and goals, and, importantly, maintenance and protection of the valuable “Philips” brand.<sup>38</sup>

161. On its website and in promotional materials, the Philips conglomerate holds itself out to the world as a unified global company that identifies itself simply as “Philips,” without distinguishing between or among the various Philips entities.<sup>39</sup> Indeed, Philips proudly proclaims: “We are a diverse team made up of some 80,000 individuals across over 100 countries, all with different backgrounds, perspectives and experiences.”<sup>40</sup>

162. Royal Philips’ effort to unite its various business segments and subsidiaries under one brand and to construct a single Royal Philips image in the public eye is evident in its use of the iconic blue Philips shield:




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<sup>38</sup> For example, in 2019, Royal Philips, Philips NA, and four other Philips entities, filed suit against a company alleging copyright infringement. In their complaint, the Philips entities held themselves out collectively as “Philips” contending that “[t]he six named plaintiffs ... are collectively in the business, *inter alia*, of developing, manufacturing, selling, supporting, maintaining, and servicing Philips’ medical imaging systems, including the proprietary hardware and software and related trade secrets that are necessary – and/or may be used – to operate, service, and repair such systems.” Complaint in *Philips v. 626 Holdings, Inc.*, 9:19-cv-81263-RS (S.D. Fla. 2019), ECF No. 1 (attached hereto as Exhibit “32”), at 5, ¶ 18.

<sup>39</sup> See generally, Royal Philips “About us” webpage (Exhibit “1” hereto).

<sup>40</sup> *Id.*

163. The Philips shield in its present form was debuted in November 2013, as a result of Royal Philips’ rebranding campaign and appears on the facade of the company’s headquarters in Amsterdam.<sup>41</sup>

164. That very same Royal Philips shield appears at the bottom of every Philips entity’s website, including the Respironics site and the Philips websites that are intended for access by foreign consumers in other countries around the world.<sup>42</sup> It also appears on the user manuals and marketing materials of the Recalled Devices.<sup>43</sup>

165. Royal Philips similarly uses its Philips “wordmark” to hold out a public image that is seamless among the various Philips entities.



166. Royal Philips has stated that “[t]he Philips wordmark is our primary and most recognized logo,” and commercial use of the wordmark is managed by the Royal Philips Brand

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<sup>41</sup> See Royal Philips Press Release, Philips unveils new brand direction centered around innovation and people (Nov. 13, 2013), <https://www.philips.com.qa/about/news/archive/standard/news/2013/20131113-Philips-unveils-new-brand-direction-centered-around-innovation-and-people.html> (last accessed Oct. 8, 2022) (attached hereto as Exhibit “160”).

<sup>42</sup> See, e.g., Philips Respironics website – About Philips Respironics (Exhibit “101” hereto); Philips Egypt website, <https://www.philips.com.eg/> (last accessed Oct. 7, 2022) (attached hereto as Exhibit “161”); Philips Australia website, [https://www.philips.com.au/?locale\\_code=en\\_au](https://www.philips.com.au/?locale_code=en_au) (last accessed Oct. 7, 2022) (attached hereto as Exhibit “162”); Philips Chile website, [https://www.philips.cl/?locale\\_code=es\\_cl](https://www.philips.cl/?locale_code=es_cl) (last accessed Oct. 7, 2022) (attached hereto as Exhibit “163”).

<sup>43</sup> See, e.g., DreamStation User Manual (Exhibit “47” hereto), at 33; REMstar SE User Manual (Exhibit “48” hereto), at 25; Trilogy 100 User Manual (Exhibit “49” hereto), at 2; Philips Respironics DreamStation Brochure (Exhibit “44” hereto), at 4; Philips Respironics DreamStation Family Brochure (Exhibit “77” hereto), at 1.

Team.<sup>44</sup> That same Philips wordmark is featured prominently at the top of the websites of various Philips entities around the world.<sup>45</sup>

167. In order to achieve consistency and a unified global presence, Royal Philips utilizes “a worldwide communication and training program” that includes “mandatory sign-off on the [company’s] General Business Principles.”<sup>46</sup> Royal Philips established these “General Business Principles” in order to “set the standard for acting with integrity at Philips.”<sup>47</sup> According to the company: these fundamentals “govern all our decisions and actions throughout the world and apply equally to our group actions and to our conduct as individuals.”<sup>48</sup>

168. Additionally, Royal Philips touts “a single standard operating model that defines how we work together effectively to achieve our company objectives – the Philips Business System (PBS).... Having a single business system increases speed and agility, and enhances standardization, quality and productivity, while driving a better, more consistent experience for our customers.”<sup>49</sup> PBS is “an interdependent, collaborative operating model that covers all aspects of how we operate,”<sup>50</sup> thereby signaling that Royal Philips intends all of its subsidiaries to depend on each other and function as one.

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<sup>44</sup> See Royal Philips website, Philips Wordmark, <https://www.philips.com/a-w/about/news/media-library/20170101-Philips-Wordmark.html> (last accessed Oct. 7, 2022) (attached hereto as Exhibit “164”).

<sup>45</sup> See, e.g., Philips Egypt website (Exhibit “161” hereto); Philips Australia website (Exhibit “162” hereto); Philips Chile website (Exhibit “163” hereto).

<sup>46</sup> See Royal Philips website, General Business Principles, <https://www.philips.com/a-w/about/investor-relations/governance/business-principles> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “33”).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> Royal Philips 2021 Annual Report (Exhibit “13” hereto), at 12.

<sup>50</sup> *Id.* at 117.

169. The PBS “is leveraged to drive operational excellence and removes irregularity caused by various operating models of recently acquired businesses.”<sup>51</sup> PBS includes “Governance” as a key aspect: “[c]lear governance, roles and responsibilities empower people to collaborate and act fast.”<sup>52</sup>

170. When Royal Philips first announced the Recall on June 14, 2021, the company stated on its website: “To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam.”<sup>53</sup>

171. Shortly after the Recall, Royal Philips’ Chief Executive Officer (“CEO”) Frans van Houten announced that: “In connection with the voluntary recall notification in June of this year, the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US.”<sup>54</sup> Mr. van Houten assured Philips’ shareholders and the public that: “We will work closely with the FDA to clarify and follow up on the inspectional findings and its recent requests related to comprehensive testing. Until we have concluded these discussions, we are not able to publicly provide further details on these responses. We remain fully committed to

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<sup>51</sup> *Id.* at 233.

<sup>52</sup> *Id.* at 12.

<sup>53</sup> Royal Philips Press Release, Philips issues recall notification\* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20210614-philips-issues-recall-notification-to-mitigate-potential-health-risks-related-to-the-sound-abatement-foam-component-in-certain-sleep-and-respiratory-care-devices.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “34”).

<sup>54</sup> Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification\* (Nov. 14, 2021), <https://www.philips.com/a-w/about/news/archive/standard/news/articles/2021/20211113-philips-provides-update-on-earlier-announced-voluntary-cpap-bipap-and-mechanical-ventilator-recall-notification.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “35”).

supporting the community of patients who rely on the affected devices, and the physicians and customers who are dedicated to meeting patient needs.”<sup>55</sup>

172. A year later, as part of its response to the Recall, Royal Philips’ CEO van Houten announced that the Philips company is “focused on further unifying and centralizing our business processes and systems to ensure that we are driving a patient centric and quality culture mindset throughout the company at all times.”<sup>56</sup>

173. The “Philips” brand is important to the company: “For some 130 years, our meaningful innovations have improved the quality of life for millions of people around the world, creating **a strong and trusted Philips brand.**”<sup>57</sup> In fact, Philips advertises that “[w]ith a 2021 brand value in excess of USD 12 billion, as defined by branding agency Interbrand, **Philips is one of the world’s strongest brands.**”<sup>58</sup>

174. In support of its contention that the company is a single, global enterprise, Philips boasts: “Over the past decade we have transformed into a focused leader in health technology.”<sup>59</sup>

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<sup>55</sup> *Id.*

<sup>56</sup> See Philips video titled “Philips CEO Frans van Houten and Chief Business Leader Connected Care Roy Jakobs talk about the various aspects of the field safety notice\*,” available at: <https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html> (last accessed Oct. 3, 2022).

<sup>57</sup> See Royal Philips “About us” webpage (Exhibit “1” hereto).

<sup>58</sup> See Royal Philips website, <https://www.philips.com/a-w/about/our-brand> (emphasis added) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “36”). Philips is ranked 57 in the Best Global Brands by Interbrand, see <https://interbrand.com/best-global-brands/philips/> (see the video on this page titled “Global Panel: Business Transformation,” where Royal Philips’ Lorraine Barber-Miller, EVP and Chief Marketing & E-Commerce Officer, discusses Philips’ global branding). In her role, Ms. Barber-Miller “[l]ead[s] 3000+ practitioners globally with an annual budget of \$1.3 billion across all...lines of business, and market segments” to “[d]riv[e] enterprise-wide marketing.” See LinkedIn Profile for Lorraine Barber-Miller, Experience section, <https://www.linkedin.com/in/lorrainebarbermiller/> (last accessed Oct. 3, 2022) (attached as Exhibit “37” hereto).

<sup>59</sup> See Royal Philips “About us” webpage (Exhibit “1” hereto).



“At Philips, our purpose is to improve people’s health and well-being through meaningful innovation. We aim to improve 2.5 billion lives per year by 2030, including 400 million in underserved communities.”<sup>60</sup>

175. Royal Philips employs a Chief Medical Officer to achieve those goals. The Chief Medical Officer performs the following functions:

- “Overall functional leadership for clinical innovation, clinical strategy, medical affairs and health economics activities of the company”;
- “work[ing] closely and collaboratively with business and functional leaders across the organization”;
- “driv[ing] the development and implementation of Philips’ medical strategies across the Health Continuum, from the perspective of consumers, patients, and providers”;
- “development of strategic relations with highly respected academic institutions and other strategic partners”;
- “clinical trial programs in support of existing and next generation products”;
- “provid[ing] clinical guidance for the development and market introduction of all new products, solutions and services”; and
- “advis[ing] Philips’ board and management in making decisions on market participation, product development, clinical development programs, business development and product launches.”<sup>61</sup>

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<sup>60</sup> *Id.*

<sup>61</sup> See LinkedIn Profile for Royal Philips Chief Medical Officer Jan Kimpen, Experience section, <https://www.linkedin.com/in/jankimpen/> (last accessed Oct. 3, 2022) (attached as Exhibit “38” hereto).

176. Philips is proud of its place in history: “We have a proud heritage of ground-breaking innovation that stretches back almost 130 years. Meaningful innovation – focused on our customers’ needs – remains at the heart of everything we do.”<sup>62</sup> The company points out that “Products come and go ... Technologies change ... But Philips is still about one thing: Creating meaningful innovation that improves people’s health and well-being.”<sup>63</sup>

177. Included as part of its long history of innovation, is Philips’ intellectual property rights.<sup>64</sup> Philips tightly controls and protects all of its intellectual property, including that of its CPAP, BiPAP, and ventilator devices, in various ways.

178. First, Royal Philips touts its Intellectual Property & Standards (IP&S) segment as an “Integrated Intellectual Asset Management” in order to **“manage all forms of IP for each of Philips’ business areas.”**<sup>65</sup> “Philips’ IP&S proactively pursues the creation of new Intellectual Property (IP) and the protection of existing IP in close co-operation with Philips’ operating businesses and Innovation & Strategy.”<sup>66</sup>

IP&S is a leading industrial IP organization providing world-class IP solutions to Philips’ businesses to support their growth, competitiveness and profitability. Royal Philips’ IP portfolio currently consists of 57,000 patent rights, 33,000 trademarks, 114,000 design rights and 2,900 domain names. Philips filed 860 new patents in 2021, with a strong focus on the growth areas in health technology services and solutions. Philips earns substantial annual income from license fees and royalties.<sup>67</sup>

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<sup>62</sup> See Royal Philips “About us” webpage (Exhibit “1” hereto).

<sup>63</sup> *Id.* at 3 (Royal Philips copyrighted webpage representing Royal Philips invested €1.8 billion in R&D in 2021 and holds 57,000 patent rights for its health technology business under the “supervision” of Royal Philips’ Executive Committee and Supervisory Board).

<sup>64</sup> *Id.*

<sup>65</sup> See Philips IP&S corporate video (Sept. 8, 2016), available at: <https://www.youtube.com/watch?v=oXGImpNSCHQ> (last accessed Oct. 3, 2022), at 1:25-1:40.

<sup>66</sup> See Philips 2021 Annual Report (Exhibit “13” hereto), at 84.

<sup>67</sup> *Id.* at 22.

179. Second, Royal Philips used a company named RIC Investments, LLC (“RIC”) for its patenting. RIC was, initially, a wholly-owned subsidiary of Respironics, Inc., and an assignee of various patents.<sup>68</sup> Thereafter, RIC became a wholly-owned subsidiary of Royal Philips including, for the last time, in a Royal Philips’ 2017 Form 20-F filing.<sup>69</sup> As of 2018, RIC no longer appears on the Form 20-F, but an entity named Philips IP Ventures B.V. is listed as a Royal Philips’ subsidiary.<sup>70</sup>

- a. Early patents believed to be related to Philips’ CPAP machines were assigned to RIC.<sup>71</sup> Similarly, early Canadian patents involving CPAP and BiPAP devices were filed by Respironics or RIC Investments and then assigned to Philips RS.<sup>72</sup>
- b. U.S. patents believed to be related to Philips’ CPAP or BiPAP devices that were filed by RIC or by Respironics, Inc. were assigned to Royal Philips.<sup>73</sup>
- c. U.S. patents believed to be related to Philips’ CPAP or BiPAP devices were filed by Royal Philips and assigned to RIC (inverse of above).<sup>74</sup> These patents reveal the comingling of inventors from Pennsylvania and the Netherlands.<sup>75</sup>

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<sup>68</sup> *Respironics, Inc. v. Invacare Corp.*, 437 F. App’x 917, 918 (Fed. Cir. 2011).

<sup>69</sup> See Royal Philips 2017 SEC 20-F filing, Exhibit 8, List of subsidiaries (Exhibit “20” hereto).

<sup>70</sup> See Royal Philips 2018 SEC Form 20-F filing, Exhibit 8, List of subsidiaries, available at: <https://www.results.philips.com/publications/ar18> (last accessed Oct. 7, 2022) (attached hereto as Exhibit “144”).

<sup>71</sup> See, e.g., Estes, *et al.*, *Method and Apparatus for Providing Positive Airway Pressure to a Patient*, Patent No. US 6,932,084 B2, Aug. 23, 2005 (attached hereto as Exhibit “145”), at 1.

<sup>72</sup> See, e.g., Canadian patents: CA 2463488 filed by RIC Investments, at 1; CA 2410248 filed by Respironics, at 1; and CA 2497915 filed by RIC, at 1. Each of these lists Philips RS North America LLC as owner (attached hereto as Exhibits “146,” “147,” and “148,” respectively).

<sup>73</sup> See, e.g., Jaffe, *et al.*, *Nasal and Oral Patient Interfaces*, Patent No. US 10,105,099 B2 (Oct. 23, 2018) (attached hereto as Exhibit “149”), at 1.

- d. U.S. patents filed by and assigned to Royal Philips have inventors listed as employees of Philips RS.<sup>76</sup>

180. Third, Royal Philips and Philips RS jointly prosecute Philips' CPAP patent infringement and unfair competition cases. For example, both Royal Philips and Philips RS were complainants in two related cases, one filed with the U.S. International Trade Commission ("USITC") and another in the District of Delaware, alleging unfair trade practices based upon infringing certain Philips' CPAP patents.<sup>77</sup> The *same* counsel represents both Royal Philips and Philips RS in these actions. Further, the USITC complaint refers to Royal Philips and Philips RS collectively as "Philips" and reflects that Royal Philips and Philips RS act as an integrated unit generally and, specifically, with respect to Philips' Sleep and Respiratory Care business, averring as follows:

9. Since its founding in 1891, Philips has dedicated significant resources to research and development for the advancement of technology used around the world through its business units including those described below. Philips strives to make the world healthier and more sustainable through innovation with the goal of improving the lives of billions of people. Philips approaches healthcare as a continuum where its technologies can be applied across activities of healthy living, prevention, diagnosis, treatment and home care as depicted in this graphic:

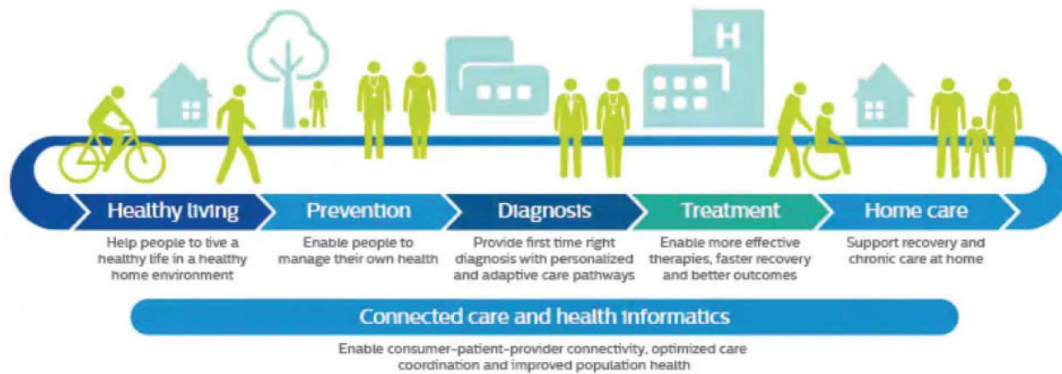
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<sup>74</sup> See, e.g., Ho, *et al.*, *Textured/Polished Respiratory Mask Seal and Mask*, Patent No. US 9,399,107 B2 (July 26, 2016) (attached hereto as Exhibit "150"), at 1.

<sup>75</sup> See, e.g., *id.*

<sup>76</sup> See, e.g., Shelly, *et al.*, *Automatic Pressure Titration*, Patent No. US 9,734,322 B2 (Aug. 29, 2017) (attached hereto as Exhibit "151"), at 1 (listing Heather Ressler as an inventor); see also Matthews, *et al.*, *Starting Pressure for Respiratory Therapy Devices*, Patent No. US 10,286,165 B2 (May 14, 2019) (attached hereto as Exhibit "152") (listing Gregory Matthews as an inventor); LinkedIn profile for Greg Matthews, <https://www.linkedin.com/in/greg-matthews-96a0491/> (attached hereto as Exhibit "153"); LinkedIn profile for Heather Ressler, <https://www.linkedin.com/in/heather-ressler-5298716/> (attached hereto as Exhibit "154").

<sup>77</sup> See *In the Matter of Certain UMTS and LTE Cellular Communication and Products Containing the Same*, Inv. No. 337-TA-1240 (USITC Dec. 17, 2020) ("USITC case") (attached hereto as Exhibit "155") and *Koninklijke Philips, N.V. v. Thales DIS AIS USA LLC et. al.*, No. 1:20-cv-01713-CFC (D. Del. Dec. 17, 2020) (attached hereto as Exhibit "156").



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12. Philips as a company is organized through various subsidiaries into four segments. These are: (1) Philips Diagnosis and Treatment; (2) Philips Connected Care and Health Informatics; (3) Philips Personal Health; and (4) an “other” segment that includes central administration and certain miscellaneous operations. See

<https://www.philips.com/a-w/about/news/archive/standard/news/press/2019/20190110-philips-realigns-the-composition-of-its-reporting-segments.html>.<sup>[78]</sup> These four segments are further broken down into several separate entrepreneurial business units. The domestic business unit that is relevant to this investigation is Philips’ Sleep (“Philips Sleep”), which is part of Philips RS North America LLC (f/k/a Respironics, Inc.), a wholly owned subsidiary of KPNV. Philips Sleep has made significant domestic investments in plant and equipment, and research and development directed to products practicing one or more claims of each of the Asserted Patents.

13. Philips Sleep falls within the Sleep and Respiratory Care business of the Philips Connected Care Segment. See <https://www.usa.philips.com/c-e/smartsleep.html>.<sup>[79]</sup> **Philips Sleep developed the hardware and software behind the Continuous Positive Airway Pressure (“CPAP”) Devices described herein, including products that have been or are being developed and sold by Philips Sleep in the United States supporting United States domestic industry.**

14. **Through this Philips Sleep business unit, Philips researches and develops sleep therapy devices with monitoring technology, develops and sells products that allow individuals to monitor and improve their health, and transfers or licenses its technologies and/or the patents that protect its technologies to customers who use the technologies in their products. As a**

<sup>78</sup> Last accessed Oct. 7, 2022.

<sup>79</sup> Last accessed Oct. 7, 2022.

result of these efforts, Philips has become a world leader in health monitoring technology and innovation, including sleep therapy devices such as its CPAP devices, and a major contributor to the United States economy and jobs.

15. For example, Philips Sleep produces products that have been or are being developed and sold in the United States, including sleep therapy devices such as CPAP devices, which are used by patients with sleep apnea and which collect various information that can be transmitted, for example, to clinicians and the user's own devices to monitor the patient's progress and manage patient compliance and therapy. The connected care system utilizing the CPAP devices (e.g., DreamStation, DreamStation2, SystemOne, DreamStation Go (DsGo), etc.) integrates UMTS and LTE Cellular Communication Modules to communicate through the cellular network to clinical products such as Care Orchestrator (predecessor EncoreAnywhere) and patient products such as DreamMapper. <https://philipsproductcontent.blob.core.windows.net/assets/20200424/adf8ec9a993041e8a097aba700e2c68e.pdf>.<sup>[80]</sup> Philips enables the care of more than 9.7 million people through cloud-based patient monitoring systems.

16. The Philips Sleep business unit expands Philips' capabilities in personal health management and supports Philips' longstanding commitment to deliver integrated solutions across the health continuum.

17. A domestic industry exists ... relating to Philips Sleep's DreamStation, DreamStation2, SystemOne, DreamStation Go (DsGo) protected by the Asserted Patents, including related products, based on **Philips Sleep's large investments made in plant and equipment, employment of labor and capital, domestic manufacturing, assembly, testing, engineering, and research and development, among other activities.**

18. A domestic industry is also in the process of being established ... relating to Philips Sleep's DreamStation2 and DreamStation Go products protected by the Asserted Patents. **Philips Sleep has taken concrete steps in the form of significant investments in plant and equipment, labor and capital, testing, engineering and research and development to establish a domestic industry in the DreamStation2 and DreamStation Go products,** which are expected to be commercially released during 2021, and therefore there is a significant likelihood that this industry will be established in the near future.<sup>81</sup>

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<sup>80</sup> Unable to access link as of Oct. 7, 2022.

<sup>81</sup> See USITC case (emphasis added).

181. Again, much of the information regarding the specific activities involving Philips' intellectual property, including Royal Philips and the individual Philips' units and their employees, is shielded from public view. Formal discovery into Philips' patent research, development, and rights would shed light on Royal Philips' control over and ownership of the intellectual property related to the Recalled Devices. However, from records that are available publicly, Royal Philips was involved with, controlled, prosecuted, and defended the intellectual property of the Recalled Devices.

182. Philips claims its "management structure combines responsible leadership and independent supervision."<sup>82</sup> The company explains that "[t]he Executive Committee operates under the chairmanship of the Chief Executive Officer and supports the Board of Management in the deployment of Philips' strategy and policies, and the achievement of its objectives and results."<sup>83</sup>

183. Royal Philips' Executive Committee – its managing body – is in charge of developing the "Risk Appetite" for the whole of the Philips Group.<sup>84</sup> The Executive Committee "identifies and manages the risks Philips face in realizing its objectives,"<sup>85</sup> referring to Royal Philips and its subsidiaries. In performing its risk management, the Executive Committee considers information from both internal and external sources, including from its subsidiaries.

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<sup>82</sup> *Id.*

<sup>83</sup> See Royal Philips website, <https://www.philips.com/a-w/about/executive-committee.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "39"). "Under the chairmanship of the President/Chief Executive Officer (CEO), and supported by the other members of the Executive Committee, the members of the Board of Management drive the company's management agenda and share responsibility for the continuity of the Philips group, focusing on long-term value creation." Philips 2021 Annual Report (Exhibit "13" hereto), at 117.

<sup>84</sup> See Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 79.

<sup>85</sup> *Id.*



184. Since at least 2017, each of the named operating segments of the Philips enterprise has had representation in the form of a “Business Leader” on Royal Philips’ Executive Committee.<sup>86</sup> For example, Mr. Roy Jakobs, who is in charge of Philips’ Connected Care businesses that include Philips RS<sup>87</sup> (and who is scheduled to become the CEO for Royal Philips on October 15, 2022<sup>88</sup>), sits on the Executive Committee.<sup>89</sup>

185. In its 2021 Annual Report, Royal Philips discusses the creation of Innovation Hubs “[t]o drive innovation, effectiveness and efficiency, and to enable locally relevant solution creation.”<sup>90</sup> The locations of these hubs are in Eindhoven (Netherlands), Cambridge (USA), Bangalore (India), and Shanghai (China).<sup>91</sup> Importantly “[t]he four hubs form a global network, together with the other smaller innovation and research sites in their respective regions, to provide access to each other’s capabilities to serve businesses, markets and customers globally.”<sup>92</sup>

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<sup>86</sup> See Royal Philips 2017 SEC Filing (Exhibit “20” hereto), at 49, 53, 58.

<sup>87</sup> See Royal Philips First-Quarter Results 2022 (Apr. 25, 2022), available at: <https://www.philips.com/a-w/about/news/archive/corpcorps/news/press/2022/philips-first-quarter-results-2022.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “40”) (“Philips has a strong program management in place led by Roy Jakobs, Chief Business Leader of the Connected Care businesses and member of Philips’ Executive Committee, to ensure the Respiration field action is executed with speed and accuracy.”).

<sup>88</sup> See Royal Philips Press Release, Philips announces CEO succession (Aug. 16, 2022), <https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2022/20220816-philips-announces-ceo-succession.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “41”).

<sup>89</sup> See Royal Philips Chief Business Leader of Connected Care, Roy Jakobs, Profile, <https://www.philips.com/a-w/about/executive-committee/roy-jakobs.html> (last accessed Oct. 9, 2022) (attached hereto as Exhibit “42”).

<sup>90</sup> Royal Philips 2021 Annual Report (Exhibit “13” hereto), at 21.

<sup>91</sup> *Id.* at 22.

<sup>92</sup> *Id.*



186. According to Royal Philips, the Eindhoven Hub is “Philips’ largest cross-functional Innovation Hub, hosting the global headquarters of most of our central innovation organizations. Many of the company’s core research programs are also run from here, as well as innovation for solution & services delivery.”<sup>93</sup>

187. The Cambridge Hub is “located at the heart of medical innovation within the North America market. It has innovation partnerships with top engineering institutions like MIT, with top clinical sites, and with government funding agencies like NIH (National Institutes of Health) and BARDA (Biomedical Advanced Research and Development Authority).”<sup>94</sup>

188. Philips’ drive for company-wide standardization extends to other aspects of the Philips enterprise. For example, “Philips runs an Integrated Supply Chain, which encompasses supplier selection and management through procurement, manufacturing across all the industrial sites, logistics and warehousing operations, as well as demand/supply orchestration.”<sup>95</sup>

189. Further, Philips invests in “embedding quality in our organizational culture as well as consolidating and standardizing our Quality Management Systems (QMS). ... With consistency of purpose, **top-down accountability**, consolidation, standardization and continuous improvement, we aim to drive the adoption of a quality mindset as well as improved quality and safety outcomes throughout the enterprise. . . .Quality is an integral part of the evaluation of all levels of management. We perform extensive programs to monitor and evaluate product performance and correct or remove any product from service that presents harm to patients or

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<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.* at 25.

users. In the event of issues we run extensive programs with the goal of recalling, repairing or replacing affected products and attempting to prevent such issues from reoccurring.”<sup>96</sup>

190. Despite conducting and presenting itself as a cohesive, unified company, with uniform business standards and operating procedures designed to maintain and protect the Philips brand, in dealings with customers, suppliers, patients, doctors, and regulatory bodies, Royal Philips has created a complex, confusing, and ever-changing labyrinth of interrelated and interconnected Philips entities and holding companies throughout the world.<sup>97</sup> Much of the information regarding the specific activities of the individual Philips units and their employees is shielded from public view. Formal discovery into Philips’ corporate structure would shed light on the level of Royal Philips’ control over and ownership of the specific entities involved in the allegations related to the responsibility for the Recalled Devices. However, from records that are available publicly, Royal Philips was involved with and controlled not only the sales and marketing of the Recalled Devices, but also the decisions regarding PE-PUR foam, and the recall of the devices containing PE-PUR foam.

### **III. JURISDICTION AND VENUE**

191. The Court has subject matter jurisdiction over the federal claims asserted herein under 28 U.S.C. § 1331. The Court has supplemental jurisdiction over the state law claims under 28 U.S.C. § 1367. The Court further has jurisdiction under 28 U.S.C. § 1331 for the RICO and Magnuson-Moss Warranty claims and under 28 U.S.C. § 2310(d) for the Magnuson-Moss Warranty claims. The Court has jurisdiction under 28 U.S.C. § 1332, as amended by the Class Action Fairness Act of 2005, because the matter in controversy exceeds \$5 million, exclusive of

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<sup>96</sup> *Id.* at 85 (emphasis added).

<sup>97</sup> Royal Philips 2020 SEC filing, Exhibit 8, List of Subsidiaries (Exhibit “16” hereto).

interest and costs, and is a class action in which Plaintiffs and some members of the Class are citizens of states different than Defendants. *See* 28 U.S.C. § 1332(d)(2)(A).

192. Each Philips Defendant has significant contacts with the Western District of Pennsylvania such that they are subject to personal jurisdiction of the Court. Further, when convenient for Royal Philips, the company concedes it is subject to personal jurisdiction of the Court. For example, in the *SoClean, Inc. v. Koninklijke Philips N.V., et al.*, 2:22-cv-542 litigation, transferred to *In re SoClean, Inc. Marketing, Sales Practices and Prod. Liab. Litig.*, MDL No. 3021 (W.D. Pa.), counsel for Royal Philips filed a Declaration stating that “KPNV [Royal Philips] acknowledged and conceded that it was subject to specific personal jurisdiction in Pennsylvania on the claims asserted by SoClean in th[at] action.”<sup>98</sup>

193. This Court has personal jurisdiction over each Philips Defendant for the additional reason that they have engaged in substantial, systematic and continuous contacts with Pennsylvania by, *inter alia*, regularly conducting and soliciting business in Pennsylvania and this District, deriving substantial revenue from products and/or services provided to persons in Pennsylvania and this District.

194. When this litigation first commenced, the same lawyers represented both Philips NA and Philips RS. Both entities argued in front of the Judicial Panel on Multidistrict Litigation for consolidation in Massachusetts, where Philips NA is headquartered. According to their joint brief, “the District of Massachusetts has the strongest nexus to the litigation.” MDL No. 3014, Dkt. No. 47 at 13 (J.P.M.L. July 29, 2021). However, they also argued that alternatively, “a clear nexus to the matter ..., the Western District of Pennsylvania is home to the other defendant,

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<sup>98</sup> *See* Declaration of William B. Monahan in Support of Motion to Dismiss, Case 2:22-mc-0152-JFC, at ECF 126-1 (attached hereto as Exhibit “43”).

Philips RS North America LLC (with headquarters in Murrysville, PA) and is also well-equipped to handle the consolidated actions.” *Id.* at 8.

195. Venue is proper in this District on account of the MDL designation pursuant to 28 U.S.C. § 1407 and under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this District.

#### **IV. FACTUAL ALLEGATIONS**

##### **A. CPAP AND BIPAP MACHINES AND VENTILATORS ARE PRESCRIBED TO TREAT BREATHING DISORDERS.**

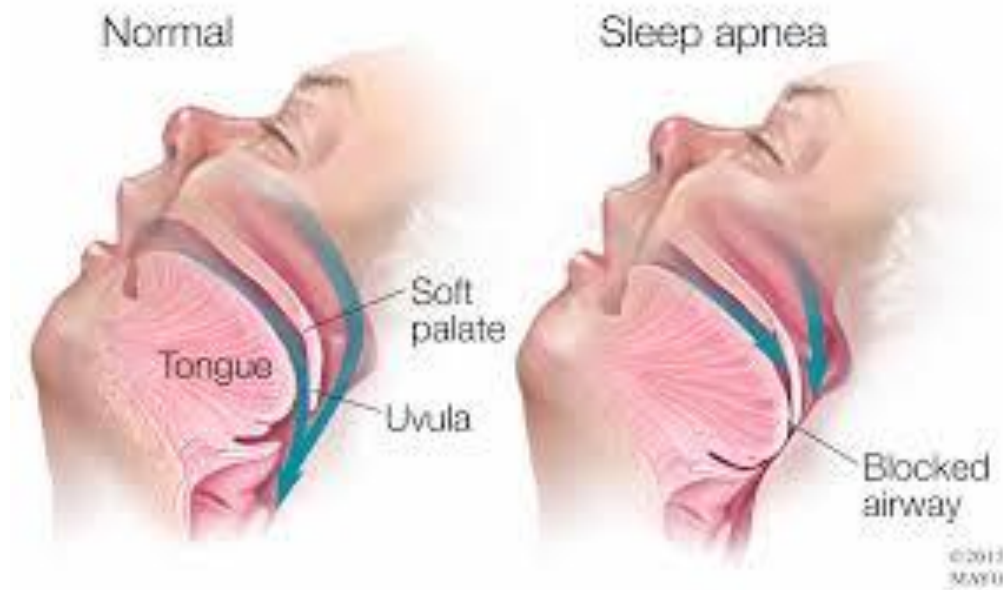
196. Sleep apnea is a sleeping disorder in which breathing is disturbed during sleep. These disturbances are called “apneas.”

197. According to the Mayo Clinic, the main types of sleep apnea are obstructive sleep apnea, central sleep apnea, and complex sleep apnea syndrome (also known as treatment-emergent central sleep apnea).

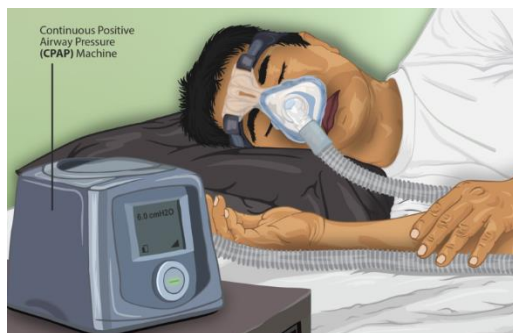
198. Obstructive sleep apnea is the most common type of sleep apnea. It occurs when the muscles in the back of the throat relax during inhalation, which causes the airway to narrow or close and prevent sufficient air from passing through. This in turn lowers the oxygen level in the blood, which causes the brain briefly to wake the body from sleep to reopen the airway. This reawakening may be so brief that the patient does not remember it, and it may be associated with snorting, choking, or gasping. It can happen anywhere from a few times per hour to once every few minutes, and can prevent the patient from reaching the deep, restful phases of sleep.

199. Central sleep apnea occurs when the brain fails to transmit signals to the breathing muscles. As a result, the body stops breathing, which can cause waking with shortness of breath, difficulty getting to sleep, or difficulty staying asleep.

200. Complex sleep apnea syndrome occurs when a patient has both obstructive sleep apnea and central sleep apnea. An image showing how an airway can be blocked as a result of sleep apnea appears below:



201. CPAP therapy is a common treatment for sleep apnea. In CPAP therapy, a machine delivers a continuous flow of air through a mask that is placed over the nose or mouth, which increases air pressure in the throat so that the airway does not collapse during inhalation. CPAP therapy assists breathing during sleep and can successfully treat sleep apnea. The illustration below shows a generic CPAP machine being used by a patient while sleeping.



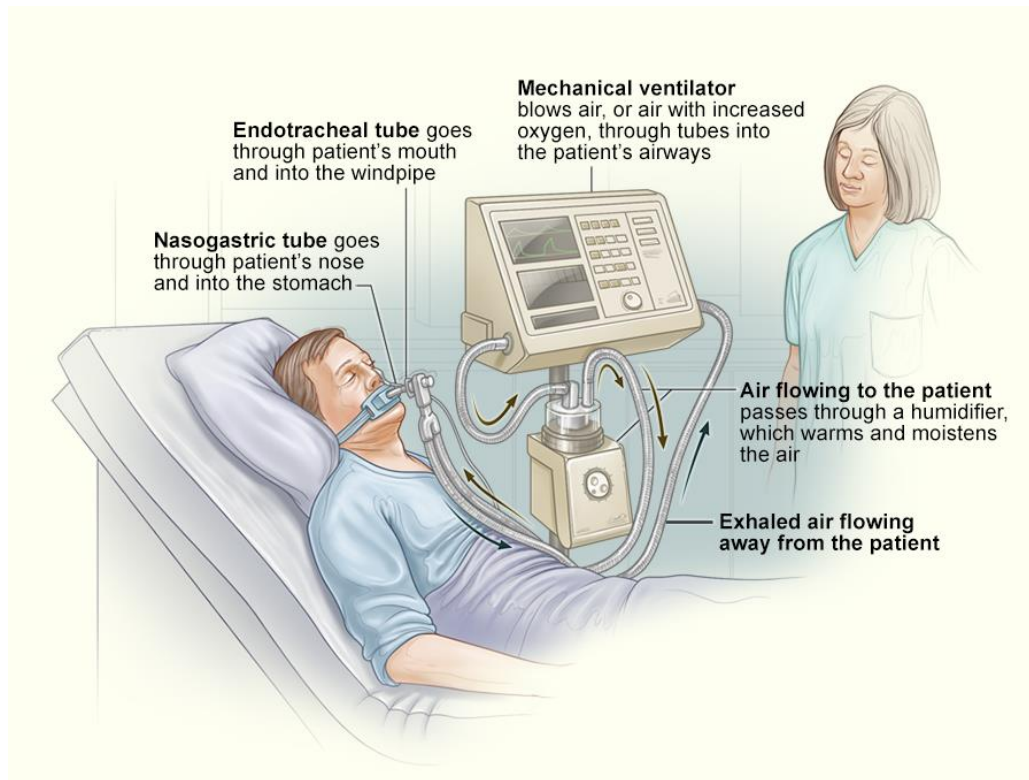
202. Another therapy to treat sleep apnea includes use of BiPAP machines, which use two different pressures – one for inhaling and one for exhaling.

203. Patients customarily place CPAP or BiPAP machines on a nearby nightstand or shelf. A hose connects the unit to a mask, which is worn over the nose or mouth during sleep.

Below is an image of a Philips DreamStation machine on a nightstand.



204. Ventilators are often used to treat respiratory failure. Ventilators push air into and out of the patient's lungs like a bellows, typically through a tube that is connected to the machine on one end and inserted through the patient's nose or mouth into the trachea on the other end. Patients are typically sedated while on ventilation because it can otherwise cause intense pain. Ventilators can also be used in other circumstances, such as during surgery when general anesthesia may interrupt normal breathing. There are also ventilators for home use. The following image from the National Institute of Health ("NIH") shows a typical ventilator and how it works:



**B. THE EVOLUTION OF CPAP, BIPAP, AND VENTILATOR DEVICES CONTAINING PE-PUR FOAM.**

205. The basic technology used in CPAP and BiPAP devices was developed in 1980 by an Australian pulmonologist, Dr. Colin Sullivan, who used it to treat dogs with respiratory problems, before the technology was adapted for humans.

206. Respironics commercialized this technology and sold the first publicly available CPAP device in 1985. ResMed, an industry competitor, followed with the release of its CPAP device in 1989.

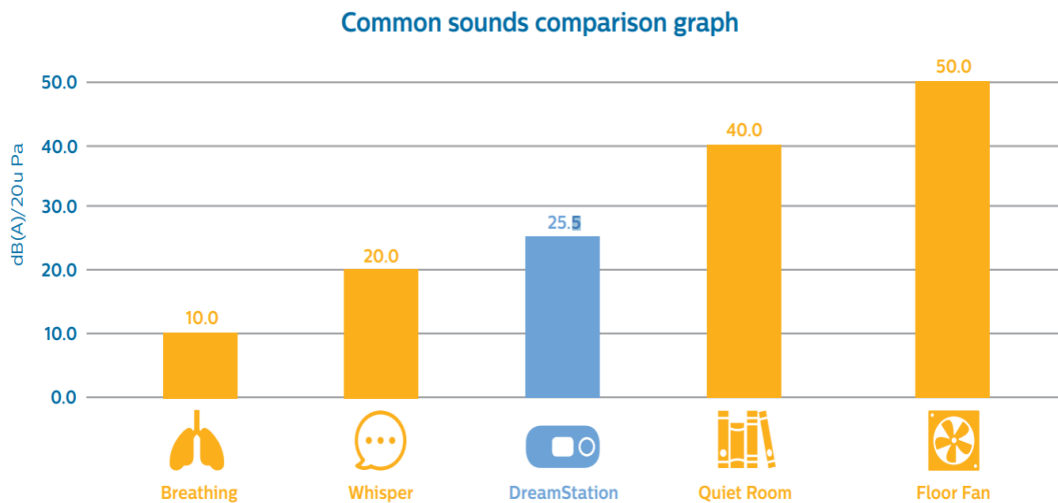
207. These first-generation CPAP and BiPAP devices created a new and commercially viable field of respiratory therapy. The devices, however, were large and noisy, resulting in an “arms-race” between manufacturers to develop devices that were smaller, more responsive to patient breathing patterns, and quieter.



208. The noise level of CPAP and BiPAP devices became a driver of adult consumer preference because loud devices interrupted the peaceful sleep of both the patient and their partner.

209. To develop the quietest devices on the market with the lowest decibel ratings, some device manufacturers including Philips filled the CPAP, BiPAP, and ventilator devices with sound abating foam to reduce the volume of noise emitted from the devices.

210. In fact, the alleged relative quiet nature of the DreamStation products with PE-PUR foam factored prominently into Philips' marketing.<sup>99</sup> Philips represents that it extensively studied and measured the amount of sound produced by DreamStation products. Philips even included an infographic indicating DreamStation products are barely louder than a whisper:<sup>100</sup>



211. Other manufacturers did not utilize foam for sound abatement, instead they utilized silencing technology to abate the sound from the devices.

<sup>99</sup> See Philips Respironics DreamStation Brochure, available at: <https://www.documents.philips.com/assets/20170523/62e4f43a1349489ba3cca77c0169c6ef.pdf> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “44”).

<sup>100</sup> See *id.* at 3.



212. Philips manufactures and sells CPAP and BiPAP machines and ventilators, among other products. According to Royal Philips' 2020 Annual Report,<sup>101</sup> Sleep & Respiratory Care ("SRC") constituted 49% of its total sales in its Connected Care line of business,<sup>102</sup> which, in turn, accounted for 28% of Royal Philips' overall sales of about €19.5 billion. Philips has sold millions of CPAP, BiPAP, and ventilator devices in the United States and elsewhere throughout the globe. In 2021, there was "a 23% decline in [Royal Philips'] Connected Care businesses. This was largely due to the Respironics recall..."<sup>103</sup>

213. Philips provides a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.<sup>104</sup>

214. Philips made the decision to use PE-PUR foam for sound abatement purposes in its CPAP, BiPAP, and ventilator devices. That decision was made for products distributed by Philips' entities throughout the globe including, but not limited to the United States, Australia, Canada, Israel, and Chile.<sup>105</sup>

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<sup>101</sup> See Royal Philips 2020 Annual Report, available at: <https://www.results.philips.com/publications/ar20> (last accessed Oct. 7, 2022) (attached hereto as Exhibit "45").

<sup>102</sup> *Id.* at 18. Prior to 2019, SRC was part of Philips' Personal Health businesses. See Royal Philips 2018 Annual Report, available at: <https://www.philips.com/c-dam/corporate/about-philips/sustainability/downloads/other/philips-full-annual-report-2018.pdf> (last accessed Oct 4, 2022) (attached hereto as Exhibit "46"), at 5.

<sup>103</sup> Royal Philips 2021 Annual Report (Exhibit "13" hereto), at 28.

<sup>104</sup> See, e.g., DreamStation User Manual (attached hereto as Exhibit "47"), at 2; REMstar SE User Manual (attached hereto as Exhibit "48"), at 2.

<sup>105</sup> See Royal Philips Q2 2022 Results, available for download at [Philips Q2 2022 Quarterly Results | Philips Results](#) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "50"), at 33.

215. Polyurethane is an organic polymer in which urethane groups connect the molecular units. It is usually formed by reacting a diisocyanate or triisocyanate with a polyol. Under certain circumstances, polyurethane may break down into a diisocyanate or triisocyanate.

216. The two main types of polyurethane are polyester and polyether. Polyester polyurethane has better shock absorption and vibration dampening properties and is commonly used for soundproofing or sound dampening.

217. It has been known for decades that polyester polyurethane is susceptible to hydrolysis, the chemical breakdown of a compound due to reaction with water, particularly in medical applications. For example, a chapter of a scientific encyclopedia published in 2013 states: “Poly(ester urethanes) were the first generation of PURs used in medical devices but were found unsuitable for long-term implants because of rapid hydrolysis of the polyester soft segment.”<sup>106</sup>

218. Polyether polyurethane, on the other hand, is less prone to hydrolysis. The same scientific encyclopedia chapter notes that polyether polyurethanes “with excellent hydrolytic stability replaced poly(ester urethanes) and have been used in medical devices for the past two decades.”<sup>107</sup>

219. There were readily available alternative designs available to Philips, other than to use PE-PUR foam in CPAP, BiPAP, and ventilator devices for sound abatement. These include, for example, other types of sound abating foam and silencing technologies that do not use foam.

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<sup>106</sup> Pal Singh Chauhan, N., and Kumari Jangid, N., “Polyurethanes and Silicone Polyurethane Copolymers,” Chapter in Encyclopedia of Biomedical Polymers and Polymeric Biomaterials, January 2013, available at: [https://www.researchgate.net/publication/236144965\\_POLYURETHANES\\_AND\\_SILICONE\\_POLYURETHANE\\_COPOLYMERS](https://www.researchgate.net/publication/236144965_POLYURETHANES_AND_SILICONE_POLYURETHANE_COPOLYMERS) (last accessed Oct. 3, 2022).

<sup>107</sup> *Id.*

220. For example, Philips' principal competitor, ResMed, uses polyether polyurethane foam or silicone-based foam, not PE-PUR foam, for sound dampening.<sup>108</sup>

**C. PHILIPS DESIGNED, MANUFACTURED, AND MARKETED ADULTERATED CPAP, BIPAP, AND VENTILATOR DEVICES.**

**1. Royal Philips Was Directly Involved With Launching And Marketing The Recalled Devices.**

221. Philips designed and manufactured CPAP and BiPAP devices and ventilators, including the Recalled Devices.

222. From as early as 2009, Royal Philips took a lead role in launching and marketing several of the Recalled Devices. It did so by “back[ing] ... launches with the requisite support in advertising and promotion”<sup>109</sup>; issuing press releases that promoted the devices; participating in medical device conferences that took place in the United States and elsewhere; and maintaining a sleepapnea.com website that educated consumers and providers on Philips devices. Royal Philips' public statements are replete with examples of this conduct.

223. On June 2, 2009, Philips Respironics issued a press release stating, “Royal Philips Electronics (NYSE:PHG, AEX: PHI) today introduced the Trilogy100 portable at-home life-support ventilator.”<sup>110</sup> The Trilogy 100 is one of the Recalled Devices. That same June 2, 2009

<sup>108</sup> See ResMed website – An update from ResMed's CEO, <https://www.resmed.com/en-us/other-manufacturer-recall-2021/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “51”).

<sup>109</sup> Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q1 2017 Koninklike Philips NV Earnings Call (Apr. 24, 2017), <https://www.results.philips.com/publications/q117/downloads/files/en/philips-first-quarter-results-2017-transcript.pdf?v=20170723194740> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “52”), at 5.

<sup>110</sup> See Philips Respironics Press Release, Philips Respironics, Philips Expands Home Healthcare Commitment with Portable Life-Support Ventilator; Offers Ease of Use, Portability and Versatility for Patient (June 2, 2009), <https://web.archive.org/web/20090827084718/http://www.prnewswire.com/mnr/respironics/38626/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “53”).

press release directed media inquiries to Steve Kelly,<sup>111</sup> who at the time, was serving as the Director of Global Public Relations and Corporate Communications of Philips Healthcare.<sup>112</sup> While in this position, he “[m]anaged all public relations and corporate communications initiatives on behalf of the largest sector of Philips Electronics while coordinating activities with the HQ team in Amsterdam.”<sup>113</sup>

224. On October 13, 2009, Philips Respironics issued a press release stating, “Royal Philips Electronics (NYSE: PHG, AEX: PHI) today introduced the next generation Philips Respironics Sleep Therapy System at Medtrade 2009, the leading conference and expo for the home medical equipment industry.”<sup>114</sup> The Sleep Therapy System referred to in press release was the System One 60,<sup>115</sup> one of the Recalled Devices.

225. On August 29, 2016, Royal Philips issued a press release that, among other things, stated that Royal Philips “will showcase its latest COPD and respiratory solutions at the upcoming European Respiratory Society International Congress (ERS) in London, from September 3-7.”<sup>116</sup>

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<sup>111</sup> *Id.*

<sup>112</sup> See LinkedIn Profile for Steve Kelly (Sept. 22, 2022), <https://www.linkedin.com/in/stvkly> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “54”).

<sup>113</sup> *Id.*

<sup>114</sup> Philips Respironics Press Release, Philips Unveils Intelligent Sleep Apnea Therapy System To Home Healthcare Industry (Oct. 13, 2009), <http://multivu.prnewswire.com/mnr/brunner/40190/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “55”).

<sup>115</sup> See *id.* (offering media images of the System One 60 device and referring to the “breakthrough System One Humidity Control” and “comfort enhance[ing] System One Resistance Control” features).

<sup>116</sup> See Royal Philips Press Release, Philips Raises Awareness for Chronic Obstructive Pulmonary Disease (COPD) with Platinum Sponsorship of Leonard Nimoy Tribute Documentary (Aug. 29, 2016), <https://www.usa.philips.com/a->

226. On September 1, 2016, Royal Philips issued a press release regarding its promotion of the DreamStation CPAP, one of the Recalled Devices, at an international trade show:

At this year's Internationale Funkausstellung (IFA) in Berlin, Germany, Royal Philips (NYSE: PHG, AEX: PHIA) today announced a range of new products . . . Key product innovations being showcased at IFA 2016 that support Philips' commitment to helping consumers stay healthy, live well and enjoy life include: . . . The Dream Family, comprised of the DreamWear mask, DreamStation CPAP (Continuous Positive Airway Pressure) device, and DreamMapper patient engagement app. . . .<sup>117</sup>

The September 1, 2016 press release directed media and others interested in obtaining further information to Netherlands-based Elena Calamo Specchia,<sup>118</sup> who at the time, was working in Royal Philips' Amsterdam office as the Royal Philips Spokesperson and Director of the Royal Philips Group Press Office.<sup>119</sup>

227. Also on September 1, 2016, Royal Philips held a press conference at the IFA trade show,<sup>120</sup> during which Netherlands-based Pieter Nota (who at the time was Royal Philips' CEO of Personal Health Businesses, Chief Marketing Officer, and Member of the Executive

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[w/about/news/archive/standard/news/press/2016/20160829-COPD-awareness-with-platinum-sponsorship-Leonard-Nimoy-tribute-documentary.html](https://www.philips.com/a-w/about/news/archive/standard/news/press/2016/20160829-COPD-awareness-with-platinum-sponsorship-Leonard-Nimoy-tribute-documentary.html) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "56").

<sup>117</sup> See Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Sept. 1, 2016), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2016/20160901-philips-introduces-a-wide-range-of-connected-personal-health-innovations-at-ifa-2016.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "57").

<sup>118</sup> *Id.*

<sup>119</sup> See LinkedIn Profile for Elena Calamo Specchia (Sept. 29, 2022), <https://nl.linkedin.com/in/elena-calamo-specchia-b3a17418> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "58").

<sup>120</sup> Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Sept. 1, 2016) (Exhibit "57" hereto).

Committee and Board of Management)<sup>121</sup> made a presentation promoting the DreamStation as well as other Philips products that were being showcased at IFA.<sup>122</sup> The press conference was live-streamed on Royal Philips' website, [www.ifa.philips.com](http://www.ifa.philips.com).<sup>123</sup>

228. On January 5, 2017, Royal Philips issued a press release announcing that “Royal Philips” was showcasing its products, including the DreamStation Go, at the International Consumer Electronics Show (CES) in Las Vegas.<sup>124</sup> The press release quoted Pieter Nota as stating, “In areas such as oral health, mother and child care, sleep and respiratory care, heart health, and home monitoring, Philips is showcasing its ecosystem of connected products and services at CES, once again demonstrating its leadership in the world of digital health.”<sup>125</sup> As with the September 1, 2016 press release, Royal Philips' Elena Calamo Specchia was again listed as the media contact.<sup>126</sup>

229. On January 24, 2017 in a Royal Philips investor call, CEO Frans van Houten remarked on the “success” of Philips' Dream Family of products and was enthusiastic about introduction of the DreamStation Go, one of the Devices at issue here:

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<sup>121</sup> See LinkedIn Profile for Pieter Nota, <https://de.linkedin.com/in/pieter-nota-5526a235> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “59”).

<sup>122</sup> See TechEvents YouTube video, Philips Press Conference Full at IFA 2016 (Sept. 1, 2016), available at: [https://www.youtube.com/watch?v=ZU5PFn91\\_oU](https://www.youtube.com/watch?v=ZU5PFn91_oU) (last accessed Oct. 3, 2022), at 8:28-10:00.

<sup>123</sup> Royal Philips Press Release, Philips Introduces a Wide Range of Connected Personal Health Innovations at IFA 2016 (Exhibit “57” hereto).

<sup>124</sup> Royal Philips Press Release, Philips Highlights Cloud-Based Innovations at the Forefront of Digital Health During CES (Jan. 5, 2017), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170105-philips-highlights-cloud-based-innovations-at-the-forefront-of-digital-health-during-ces.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “60”).

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

Building on the success of the Philips' integrated Dream Family solution in the United States, Europe and Japan, we recently introduced a Philips DreamStation Go portable CPAP solution. DreamStation Go is a compact and lightweight device designed to provide sleep therapy for travelers with obstructive sleep apnea.<sup>127</sup>

230. On March 7, 2017, Royal Philips issued a press release in which "Royal Philips . . . announced the expansion of its Dream Family of products with the new DreamStation Advanced Therapies" products, which consisted of "the DreamStation Advanced Therapies BiPAP autoSV and AVAPS devices,"<sup>128</sup> both of which are Recalled Devices at issue in this litigation.

231. On April 11, 2017, Royal Philips issued a press release in which "Royal Philips . . . announced the launch of DreamStation Go."<sup>129</sup> Royal Philips' Elena Calamo Specchia was again listed as one of the media contacts on the press release.<sup>130</sup>

232. On April 24, 2017, in a Royal Philips investor call, Royal Philips CFO, EVP and Member of the Board of Management Abhijit Bhattacharya<sup>131</sup> informed investors that Royal

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<sup>127</sup> Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q4 2016 Koninklike Philips NV Earnings Call (Jan. 24, 2017), available at: <http://www.philips.com/static/qr/2016/q4/philips-fourth-quarter-results-2016-transcript.pdf> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "61"), at 5.

<sup>128</sup> See Royal Philips Press Release, Philips expands its award-winning DreamStation platform to treat patients with most complex sleep and breathing needs (Mar. 7, 2017), <https://www.prnewswire.com/news-releases/philips-expands-its-award-winning-dreamstation-platform-to-treat-patients-with-most-complex-sleep-and-breathing-needs-300418735.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "62").

<sup>129</sup> See Royal Philips Press Release, Philips Simplifies Travel for Sleep Apnea Patients with New Compact and Connected DreamStation Go Sleep Therapy Device (Apr. 11, 2017), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170411-philips-simplifies-travel-for-sleep-apnea-patients-with-new-compact-and-connected-dreamstation-go-sleep-therapy-device.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "63").

<sup>130</sup> *Id.*

Philips would launch the DreamStation Go and provide financial support for the advertising and promotion of the device:

As Frans [van Houten] mentioned, in Health & Wellness, we have a solid pipeline of new product introductions . . . We will also launch the Philips DreamStation Go portable CPAP solutions. We will back these launches with the requisite support in advertising and promotion, which will have a dampening effect on the results of Personal Health in the second quarter. However, I hasten to add that we do expect to have continued improvements in operating results for Personal Health.<sup>132</sup>

233. On September 8, 2017, Royal Philips issued a press release announcing that, “At the European Respiratory Society (ERS) International Congress 2017 in Milan, Italy (September 9-13), Royal Philips (NYSE: PHG, AEX: PHIA), a global leader in health technology, will showcase and announce the global expansion of its suite of cutting-edge connected respiratory and sleep solutions,” which included “the brand-new DreamStation Go,” and the “DreamStation BiPAP AutoSV and AVAPS solutions.”<sup>133</sup>

234. On November 13, 2017, Royal Philips issued a press release announcing that “Royal Philips” would be showcasing several new medical products, including the DreamStation Go, at the 2017 MEDICA World Forum for Medicine in Düsseldorf, Germany.<sup>134</sup> The press

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<sup>131</sup> See Royal Philips webpage for Abhijit Bhattacharya, <https://www.philips.com/a-w/about/executive-committee/abhijit-bhattacharya.html> (last accessed Oct. 10, 2022) (attached hereto as Exhibit “64”). Mr. Bhattacharya is based in Eindhoven, the Netherlands. *Id.*

<sup>132</sup> Thomson Reuters StreetEvents, Edited Transcript, PHIA.AS – Q1 2017 Koninklike Philips NV Earnings Call (Apr. 24, 2017) (Exhibit “52” hereto), at 5.

<sup>133</sup> See Royal Philips Press Release, Philips showcases expanding connected respiratory and sleep solutions at ERS 2017 (Sept. 8, 2017), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20170908-philips-showcases-expanding-connected-respiratory-and-sleep-solutions-at-ers-2017.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “65”).

<sup>134</sup> See Royal Philips Press Release, Philips innovations at MEDICA 2017 connect people, technology and data across the health continuum (Nov. 13, 2017), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20171113-philips->



release quoted Frans van Houten as stating that “[t]he intelligent sleep therapy, respiratory care and ultrasound solutions we are showcasing at this year’s MEDICA bridge important transitions from healthy living to diagnosis, and clinical treatment to home care and chronic disease management, allowing patients to return home and enjoy the most out of life as quickly as possible.”<sup>135</sup> As with other similar press releases, Royal Philips’ Elena Calamo Specchia was listed as the media contact.<sup>136</sup>

235. On November 14, 2017, Royal Philips issued a press release promoting its involvement in World COPD Day.<sup>137</sup> The press release also promoted the DreamStation Advanced Therapies products and the Trilogy hospital-to-home ventilators.<sup>138</sup> Royal Philips’ Elena Calamo Specchia is again listed as the media contact.<sup>139</sup>

236. On January 29, 2018, Royal Philips issued a press release announcing that “Royal Philips” was participating in the 2018 Arab Health Exhibition and Congress on January 29, 2018 through February 1, 2018, and was showcasing several Philips products, including the

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[innovations-at-medica-2017-connect-people-technology-and-data-across-the-health-continuum.html](#) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “66”).

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> See Royal Philips Press Release, Philips launches global education and empowerment effort for World COPD Day (Nov. 14, 2017), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2017/20171114-philips-launches-global-education-and-empowerment-effort-for-world-copd-day.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “67”).

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

DreamStation Go.<sup>140</sup> The press release directed media inquiries to Netherlands-based Joost Maltha,<sup>141</sup> as Royal Philips' Senior Global Press Officer, Director of Communications.<sup>142</sup>

237. On April 16, 2019, Royal Philips issued a press release announcing that Philips would be promoting "its latest offerings" at the Medtrade show in Las Vegas, Nevada in the Spring of 2019.<sup>143</sup> Philips featured its "new, patient-focused DreamStation Go Heated Humidifier and DreamWisp" "designed to further enhance effective and efficient care for patients with chronic respiratory and sleep conditions."<sup>144</sup>

238. In addition, from as early as September 2014 until the present, Royal Philips has maintained the website SleepApnea.com, which educates consumers and providers on sleep apnea and the various treatment devices offered by Philips.<sup>145</sup>

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<sup>140</sup> See Royal Philips Press Release, Philips Breaks Health Technology Boundaries at Arab Health 2018 (Jan. 29, 2018), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2018/20180129-philips-breaks-health-technology-boundaries-at-arab-health-2018.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "68").

<sup>141</sup> *Id.*

<sup>142</sup> See LinkedIn Profile for Joost Maltha (Sept. 29, 2022), <https://nl.linkedin.com/in/joostmaltha> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "69").

<sup>143</sup> See Royal Philips Press Release, Philips showcases new opportunities for Home Medical Equipment providers at Medtrade Spring (Apr. 16, 2019), <https://www.usa.philips.com/a-w/about/news/archive/standard/news/press/2019/20190416-philips-showcases-new-opportunities-for-home-medical-equipment-providers-at-medtrade-spring.html> (last accessed Oct. 9, 2022) (attached hereto as Exhibit "70").

<sup>144</sup> *Id.*

<sup>145</sup> See sleepapnea.com landing page, archived on Sept. 28, 2014 at <https://web.archive.org/web/20140928073021/http://www.sleepapnea.com/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "71"). The landing page of the website contains a copyright for Royal Philips: "© Koninklijke Philips N.V., 2004 - 2014. All rights reserved.)."

## 2. Philips Obtained Clearances For the Recalled Devices.

239. Philips obtained 510(k) clearance from the Food and Drug Administration (“FDA”) for various CPAP, BIPAP and ventilator devices.

240. 510(k) clearance generally only requires the manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments of 1976 to the Food Device Cosmetic Act (MDA) of its intent to market a device at least 90 days prior to the device’s introduction on the market, and to explain the device’s substantial equivalence to a pre-MDA predicate device. The FDA may then “clear” the new device for sale in the United States.

241. Philips utilized the 510(k) process to receive clearances for each of its Recalled Devices except the E30 ventilator which was marketed under an Emergency Use Authorization (EUA).

242. With respect to the EUA for the E30 ventilator, on March 24, 2020, in response to “concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in healthcare settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic,”<sup>146</sup> the FDA issued an umbrella EUA of ventilators and related equipment. On April 8, 2020, this EUA was extended to the E30 ventilator.<sup>147</sup> A device may be authorized under this umbrella EUA if it “may be effective” in diagnosing, treating, or preventing COVID-19<sup>148</sup>; and

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<sup>146</sup>See Food and Drug Administration, Ventilators and Ventilator Accessories EUAs, <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas> (last accessed Oct. 3, 2022).

<sup>147</sup> *Id.*

<sup>148</sup> See Food and Drug Administration, Emergency Use Authorization Letter (Mar. 24, 2020), available at: <https://www.fda.gov/media/136423/download> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “143”).

according to the FDA, “[t]he ‘may be effective’ standard for EUAs provides for a lower level of evidence than the ‘effectiveness’ standard that FDA uses for product approvals.”

243. With respect to the 510(k) process for each of the other Recalled Devices, Philips included data, testing, and biocompatibility results along with its applications to claim substantial equivalence to a predicate device.

244. Upon reviewing the submissions, the FDA determined Philips’ devices were substantially equivalent to a predicate device.

245. After the devices were sold, Philips had a duty to find, investigate, and report adverse events to the FDA. For example, 21 C.F.R. part 803 requires Philips to conduct a thorough investigation of each event. This duty is triggered when Philips becomes aware of information from any source that reasonably suggests that its device (1) may have caused or contributed to a death or serious injury, or (2) has malfunctioned, and, this device or a similar device it markets, is likely to cause or contribute to a death or serious injury, if the malfunction were to recur. 21 C.F.R. § 803.50.

246. Additionally, as a manufacturer, Philips has unique knowledge concerning the frequency, severity and predictability of the complications and risks associated with its devices. Accordingly, Philips has post-market responsibility under the FDA Regulations related to complaint handling, investigation and reporting to the FDA, including but not limited to:

- a. 21 C.F.R. § 803.10 (for example, § 803.10(c) requires adverse events to be reported by a manufacturer in set time frames from 5 to 30 days when the event becomes known);
- b. 21 C.F.R. § 803.17 (“Medical device manufacturers must develop and implement standardized medical device reporting procedures so that timely evaluation of events and communication of findings can occur.”);
- c. 21 C.F.R. § 803.18 (§ 803.18(d)(1) requires a device distributor to maintain complaint files and records, including any written, electronic or oral

communication, either received or generated by the distributor, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device.);

- d. 21 C.F.R. § 803.20 (“Manufacturers must timely communicate a reportable event. Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.”);
- e. 21 C.F.R. § 803.3 (“If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within 30 calendar days or that is required to be reported within 5 work days because we had requested reports in accordance with 803.53(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.”);
- f. 21 C.F.R. § 803.50 ((a) “If you are a manufacturer, you must report to the FDA information required by 803.52 in accordance with the requirements of 803.12(a), no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.” Subsection (b) defines information reasonably known to a manufacturer to include: “[a]ny information that you can obtain by contacting a user facility, importer, or other initial reporter; . . . [a]ny information in your possession; or . . . [a]ny information that you can obtain by analysis, testing, or other evaluation of the device.” Section 803.50 continues: “(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters. (3) You are also responsible for conducting an investigation of each event and evaluating the cause of the event. If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56 in accordance with the requirements of 803.12(a).”);

- g. 21 C.F.R. § 803.52 (detailed individual and device information must be submitted for each adverse event);
- h. 21 C.F.R. § 803.53 (information regarding detailed individual and device information must be submitted in a timely manner when remedial action may be required);
- i. 21 C.F.R. § 803.56 (supplemental reporting must be done if additional information is learned that became known after the initial report was submitted); and
- j. 21 C.F.R. § 820.198 (“Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of: (1) Whether the device failed to meet specifications; (2) Whether the device was being used for treatment or diagnosis; and (3) The relationship, if any, of the device to the reported incident or adverse event”).

247. In addition, there are state law duties to monitor, investigate, evaluate and timely report injuries and other important safety information regarding a medical device, which Philips violated when it failed to: monitor, investigate and report PE-PUR foam degradation risk and incidents; take the necessary steps to continually evaluate the safety, effectiveness and reliability of its Recalled Devices; and take necessary steps to warn, strengthen its warnings, and take other measures to assure compliance with its obligations.

### **3. The Recalled Devices Are “Adulterated” According To The FDA’s Findings And, Therefore, They Are Worthless.**

248. The FDA determined that the Recalled Devices failed to comply with “current good manufacturing practice” requirements (“GMPs”) codified in FDA regulations.<sup>149</sup> Devices

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<sup>149</sup> See Food and Drug Administration 518(b) Notice Letter to Philips Respironics, May 2, 2022 (hereinafter “518(b) Notice”), available for download at

that are not manufactured in compliance with FDA’s GMPs “shall be deemed adulterated.” 21 U.S.C. § 351(h); *see id.* § 360j(f)(1) (authorizing FDA to issue regulations prescribing GMP requirements). Title 21 of the U.S. Code prohibits the sale, receipt, or delivery of “adulterated” devices. *See* 21 U.S.C. § 331(a) & (c). Accordingly, the Recalled Devices were adulterated and prohibited for sale, receipt, or delivery.

249. Specifically, the FDA determined that Philips’ manufacture of the Recalled Devices failed to comply with the GMPs imposed by FDA’s “Quality System Regulation” (“QSR”) “since at least November 2015.”<sup>150</sup> The QSR required Philips to “establish and maintain procedures for implementing corrective and preventative action” for the Recalled Devices that satisfy seven criteria. 21 C.F.R. § 820.100(a)(1)-(7).

250. In addition to the FDA’s determination that the Recalled Devices violated the QSR requirements codified at 21 C.F.R. § 820.100, the Recalled Devices were “adulterated,” and their sale prohibited, under 21 U.S.C. § 351(c), which bans a device as adulterated if its “purity or quality falls below[] that which it purports or is represented to possess.” 21 U.S.C. § 351(c).

251. There is no dispute that the Recalled Devices “fall[] below” their represented quality. *See* 21 U.S.C. § 351(c). Philips sold the Recalled Devices as, *inter alia*, “clinically proven” treatments for sleep disorders.<sup>151</sup> But in its Recall and elsewhere, Philips admits that

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<https://www.fda.gov/media/158129/download> (attached hereto as Exhibit “72”), at 6 (citing 21 CFR § 820.100).

<sup>150</sup> *Id.* at 6, 10.

<sup>151</sup> *See, e.g.*, Philips US Product page, DreamStation BiPAP autoSV (“DreamStation BiPAP autoSV[’s] . . . clinically proven algorithm provides support when needed.”), <https://www.usa.philips.com/healthcare/product/HCAHX900T15/dreamstation-bipap-autosv-servo-ventilation-system> (last accessed Oct. 4, 2022) (attached hereto as Exhibit “73”); Philips US DreamStation Go - Features (“DreamStation Go includes the same clinically-proven Flex pressure-relief technologies, therapy algorithms and event detection found in our DreamStation and System One PAP therapy devices.”),

their use may cause “serious injury which can be life-threatening, cause permanent impairment, and/or require medical intervention to preclude permanent impairment.”<sup>152</sup> As such, the Recalled Devices were undisputedly adulterated and unsalable pursuant to 21 U.S.C. § 351(c).

252. Further, the FDA’s investigation revealed that Philips’ incorporation of PE-PUR foam in the Recalled Devices at all times violated other subdivisions of the QSR, minimally including:

- a. 21 C.F.R. § 820.70(h) (requiring manufacturers to “establish and maintain procedures for the use and removal of” manufacturing materials that “could reasonably be expected to have an adverse effect on product quality”);
- b. 21 C.F.R. § 820.30(c) (requiring manufacturers to “establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device”); and
- c. 21 C.F.R. § 820.30(g) (requiring manufacturers to “establish and maintain procedures for validating the device design,” including “that devices conform to defined user needs and intended uses”).

253. Philips’ failure to comply with the FDA’s QSR (and, concomitantly the FDA’s GMPs) establishes that the Recalled Devices were “adulterated” and should not have been sold in the first instance. Each violation of the QSR furnishes an independent basis to find the Recalled Devices were “adulterated” within the meaning of Title 21. *See* 21 U.S.C. §§ 351(h) & 360j(f)(1).

254. Adulterated devices that put users at risk of life-threatening injuries, like the Recalled Devices here, are worthless because they can neither be demanded nor supplied: they cannot be legally sold, received, or delivered in interstate commerce. 21 U.S.C. § 331(a) & (c).

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<https://www.usa.philips.com/healthcare/product/HCEUG502S15/dreamstation-go-portable-pap-therapy-system#features> (last accessed Oct. 5, 2022) (attached hereto as Exhibit “74”).

<sup>152</sup> Philips Recall Notices issued June 14, 2021 (Exhibit “4” hereto).



**D. PE-PUR FOAM POSES SERIOUS HEALTH RISKS TO USERS OF PHILIPS DEVICES.**

255. Philips has belatedly revealed that the PE-PUR foam in the Recalled Devices degrades and exposes patients to toxic particles and gases. Such exposure has harmed hundreds of thousands of patients across the United States who used the Recalled Devices.

256. Patients who used Recalled Devices, including all of the individual Plaintiffs, are now at risk of developing cancer and other serious health conditions in the future.

257. On the same day as the Recall – June 14, 2021 – Philips released an announcement entitled “Clinical information for physicians.” In this announcement, Philips disclosed that it “has received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask).”<sup>153</sup> The PE-PUR foam is black, and when it breaks down, it can release black particles.<sup>154</sup> The announcement stated that the foam breakdown “may lead to patient harm and impact clinical care,”<sup>155</sup> explaining:

While there have been limited reports of headache, upper airway irritation, cough, chest pressure and sinus infection that may have been associated with the foam, based on lab testing and evaluations, *it may be possible that these potential health risks could result in a wide range of potential patient impact, from transient potential injuries, symptoms and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.*<sup>156</sup>

258. The announcement mentioned two types of hazards from the foam in the devices: dangers from foam degradation and dangers from release of VOCs.

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<sup>153</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information for physicians (June 14, 2021) (Exhibit “7” hereto), at 4.

<sup>154</sup> *Id.* at 3.

<sup>155</sup> *Id.* at 1.

<sup>156</sup> *Id.* at 2 (emphasis added).

259. First, the announcement described dangers arising from foam degradation exposure:

**Potential Hazard:** Philips has determined from user reports and lab testing that under certain circumstances the foam may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user of its Continuous Positive Airway Pressure (CPAP), BiLevel Positive Airway Pressure (BiLevel PAP) and Mechanical Ventilator devices. The foam degradation may be exacerbated by environmental conditions of higher temperatures and humidity in certain regions. Unauthorized cleaning methods such as ozone may accelerate potential degradation.

The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

- Toluene Diamine
- Toluene Diisocyanate
- Diethylene glycol.<sup>157</sup>

260. The inhalation of extremely fine particulates, even non-toxic particulates, can lead to adverse health outcomes. The Environmental Protection Agency ("EPA") notes that exposure to particles less than 10 micrometers can be linked to a variety of health problems including: aggravated asthma, decreased lung function, increased respiratory symptoms, and cardiac related diseases."<sup>158</sup>

261. On July 8, 2021, Philips released an update to a global supplemental clinical information document that contained results based on its own testing of the affected devices, stating that: "According to analysis performed by Philips, the majority of particulates are of a size ( $>8\text{ }\mu\text{m}$ ) . . . Smaller particulates ( $<1\text{-}3\text{ }\mu\text{m}$ ) are capable of diffusing into deep lung tissue

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<sup>157</sup> *Id.* at 3-4.

<sup>158</sup> See [Health and Environmental Effects of Particulate Matter \(PM\) | US EPA](#) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "75").

and deposit into the alveoli. During testing performed by an outside laboratory on lab degraded foam, the smallest particulate size identified was 2.69  $\mu\text{m}$ .<sup>159</sup>

262. The purity of the air coming from a breathing device to a patient is highly important and material. Indeed, Philips advertises the filtration systems in its devices, for example, noting them on a diagram in its DreamStation Family Brochure.<sup>160</sup> Philips' filtration system, however, does not filter out the particles described above.

263. In addition to the hazards created by the inhalation of extremely fine particulates, Philips has admitted that the particulates created via PE-PUR foam degradation contain toxic compounds such as toluene diamine, toluene diisocyanate, and diethylene glycol.<sup>161</sup> As discussed in more detail below, these compounds are toxic and/or carcinogenic when inhaled or ingested.

264. Philips concluded in its Health Hazard Evaluations ("HHEs") regarding the PE-PUR foam degradation risk that "[b]ased on the cytotoxicity and genotoxicity results and toxicological risk assessment, combined with [the] conclusion that particles are likely to reach the upper airway and potentially the lower respiratory track [*sic*], a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient populations is a severity level 3 (Crucial) for both short/intermediate and long term exposure."<sup>162</sup>

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<sup>159</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update, Clinical Information (July 8, 2021), available at: [philips-global-supplemental-clinical-information-document.pdf](https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "76"), at 2.

<sup>160</sup> See Philips Respironics DreamStation Family Brochure, available at: <https://www.documents.philips.com/assets/20180205/15ef65ad106d4ddc88fca87e0134dc60.pdf> (last accessed Oct. 9, 2022) (attached hereto as Exhibit "77").

<sup>161</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update, Clinical Information (July 8, 2021) (Exhibit "76" hereto), at 1.

<sup>162</sup> 518 (b) Notice (Exhibit "72" hereto), at 3-4.

265. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

266. Further, [REDACTED]

[REDACTED]

[REDACTED]

267. Philips' HHEs note that the harm due to foam degradation "'may not be immediately recognizable and may not be something that the customer would/could report,' adding that certain harms 'may not be easily linked to the hazardous situation or device use in general'—and that in the case of genetic mutations in particular, 'a presumed lag time from exposure to harm development may make it difficult for patients to attribute their individual harm to the device usage.'"<sup>165</sup>

268. The second hazard is the release of VOCs, that is, toxic and carcinogenic chemical emissions from the PE-PUR foam. Philips explained:

**Potential Hazard:** Lab testing performed for and by Philips has also identified the presence of VOCs which may be emitted from the sound abatement foam component of affected device(s). VOCs are emitted as gases from the foam included in the CPAP, BiLevel PAP and MV devices and may have short- and long-term adverse health effects.

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<sup>163</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<sup>164</sup> [REDACTED]

[REDACTED]

[REDACTED]

<sup>165</sup> 518 (b) Notice (Exhibit "72" hereto), *Id.* at 5.

Standard testing identified two compounds of concern (COC) may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

- Dimethyl Diazine
- Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl).<sup>166</sup>

269. In addition to these two compounds, Philips has also found high levels of formaldehyde, a known carcinogen, in analyses of the Recalled Devices. Collectively, these compounds released by PE-PUR foam—formaldehyde, toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)—are referred to herein as the “Foam Toxins.”

270. Philips admitted that the risks of these VOCs include: “irritation and airway inflammation, and this may be particularly important for patients with underlying lung diseases or reduced cardiopulmonary reserve” and may lead to the following symptoms: “headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects,” as well as “adverse effects to other organs” such as kidney and liver.<sup>167</sup>

271. It is beyond reasonable dispute that patients using the Recalled Devices were exposed to harmful particulates and the toxic Foam Toxins. As detailed below, each of the Foam Toxins poses a serious health hazard to users of the Recalled Devices.

### **1. Formaldehyde Is A Known Carcinogen.**

272. Although Philips has not publicly acknowledged that formaldehyde is used in the manufacturing process for PE-PUR foam or is a byproduct of PE-PUR foam degradation,

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<sup>166</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information for physicians (June 14, 2021) (Exhibit “7” hereto), at 4-5.

<sup>167</sup> *Id.* at 4, 5.

Philips' internal testing (dated May 22, 2019) reported the presence of formaldehyde in analyses of its DreamStation 1 devices, finding "tolerable limits of the Formaldehyde compound were exceeded during initial operation, as well as at the [redacted]."<sup>168</sup>

273. Formaldehyde has been classified as carcinogenic to humans (Group 1)<sup>169</sup> by the International Agency for Research on Cancer ("IARC") since 2006.<sup>170</sup> Governmental authorities in the United States have reached similar conclusions: the National Toxicology Program in the United State Department of Health and Human Services ("NTP") has classified formaldehyde as a known human carcinogen since 2011<sup>171</sup>; and the EPA has considered formaldehyde to be a probable human carcinogen (Group B1) since 1989.<sup>172</sup>

274. There is extensive research, including dozens of human epidemiological studies, showing an association between formaldehyde exposure and numerous forms of cancer, including: nasopharyngeal cancer; sinonasal cancer; leukemia; lung cancer;

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<sup>168</sup> See 483 Report (Exhibit "5" hereto), at 6.

<sup>169</sup> The IARC, an agency of the World Health Organization, groups carcinogenic and potentially carcinogenic substances into five categories: Group 1, carcinogenic to humans; Group 2A, probably carcinogenic to humans; Group 2B, possibly carcinogenic to humans; Group 3, not classifiable as to its carcinogenicity to humans; and Group 4, probably not carcinogenic to humans. International Agency for Research on Cancer, *Agents Classified by the IARC Monographs, Volumes 1–129*, IARC (last updated July 1, 2022), available at: <http://monographs.iarc.fr/ENG/Classification/index.php> (last accessed Oct. 3, 2022). The EPA uses an equivalent grouping system of five categories (Groups A-E). See *Risk Assessment for Carcinogenic Effects*, EPA.com, available at: <https://www.epa.gov/fera/risk-assessment-carcinogenic-effects> (last accessed Oct. 3, 2022).

<sup>170</sup> *Formaldehyde*, IARC Monograph – 100F, IARC, available at: <https://monographs.iarc.who.int/wp-content/uploads/2018/06/mono100F-29.pdf> (last accessed Oct. 3, 2022).

<sup>171</sup> *Formaldehyde*, Report on Carcinogens, NTP, available at: <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf> (last accessed Oct. 3, 2022).

<sup>172</sup> See <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/formaldehyde/formaldehyde-fact-sheet#r1> (last accessed Oct. 3, 2022).

lymphohematopoietic cancers (other than leukemia); nasal, oral, and throat cancers (other than nasopharyngeal and sinonasal cancers); brain cancer; hepatic cancer; esophageal cancer; thyroid cancer; and pancreatic cancer.<sup>173</sup> Additionally, exposure to formaldehyde appears to have a strong causal relationship to asthma.<sup>174</sup>

## **2. Toluene Diisocyanate Is A Likely Carcinogen.**

275. Toluene diisocyanates (“TDIs”) are used primarily to manufacture flexible polyurethane foams such as PE-PUR foam. Philips has recognized that PE-PUR foam releases TDIs as it degrades.<sup>175</sup>

276. TDI is classified as possibly carcinogenic to humans (Group 2B) by IARC.<sup>176</sup> The United States Center for Disease Control (“CDC”), Occupational Safety and Health Administration (“OSHA”), and National Institute for Occupational Safety and Health (“NIOSH”) also regard TDI as a potential human carcinogen based on tumorigenic responses in TDI treated rats and mice.<sup>177</sup> The EPA has taken action under the Toxic Substances Control Act

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<sup>173</sup> See, e.g., *Formaldehyde*, Report on Carcinogens, NTP, available at: <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/formaldehyde.pdf>; *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC> (last accessed Oct. 3, 2022).

<sup>174</sup> See, e.g., *1910.1048 App C - Medical surveillance – Formaldehyde*, OSHA.com, available at: <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1048AppC> (last accessed Oct. 3, 2022).

<sup>175</sup> See Royal Philips Informational PDF, *Sleep and Respiratory Care update: Clinical information for physicians* (June 14, 2021) (Exhibit “7” hereto), at 4; Royal Philips Informational PDF, *Sleep and Respiratory Care update: Clinical Information* (July 8, 2021) (Exhibit “76” hereto), at 1 (“[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include ... toluene diisocyanate isomers (TDI)”).

<sup>176</sup> *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at <https://publications.iarc.fr/publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf> (last accessed Oct. 3, 2022).

<sup>177</sup> See, e.g., *Toluene diisocyanates*, Report on Carcinogens, NTP, available at: <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf> (last accessed Oct. 3,

to allow oversight of the use of TDI in consumer products.<sup>178</sup> NTP classifies TDI as “reasonably anticipated to be a human carcinogen” based on sufficient evidence of carcinogenicity from studies in experimental animals.<sup>179</sup> The European Union warns that TDI “is fatal if inhaled.”<sup>180</sup>

277. Administration of TDI by stomach tube caused liver tumors (hepatocellular adenoma) in female rats and mice, benign tumors of the mammary gland (fibroadenoma) and pancreas (islet-cell adenoma) in female rats, and benign tumors of the pancreas (acinar-cell adenoma) in male rats. It also increased the combined incidences of benign and malignant tumors of subcutaneous tissue (fibroma and fibrosarcoma) in rats of both sexes and of the blood vessels (hemangioma and hemangiosarcoma) in female mice.<sup>181</sup> Exposure to TDI also has been documented to cause respiratory irritation, asthma, and lung damage.<sup>182</sup>

### 3. Toluene Diamine Is A Likely Carcinogen.

278. Philips has recognized that PE-PUR foam releases toluene diamine (“TDA”) as it

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2022); *Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), available at: <https://www.cdc.gov/niosh/docs/90-101/default.html> (last accessed Oct. 3, 2022).

<sup>178</sup> See <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-toluene-diisocyanate-tdi-and-related#action> (last accessed Oct. 3, 2022).

<sup>179</sup> See <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf> (last accessed Oct. 3, 2022).

<sup>180</sup> <https://echa.europa.eu/substance-information/-/substanceinfo/100.043.369> (last accessed Oct. 3, 2022).

<sup>181</sup> See <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/toluenediisocyanates.pdf>. (last accessed Oct. 3, 2022).

<sup>182</sup> See, e.g., *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at <https://publications.iarc.fr/publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf> (last accessed Oct. 3, 2022).



degrades.<sup>183</sup> Additionally, TDA is a hydrolysis product of TDI.

279. IARC has classified TDA as possibly carcinogenic to humans (Group 2B),<sup>184</sup> and the EPA classifies it as a probable human carcinogen.<sup>185</sup> The European Union has concluded that TDA “cannot be considered safe for use” even as a hair dye, let alone breathed into the lungs for many hours each night.<sup>186</sup> The NTP classifies TDA as reasonably anticipated to be a human carcinogen based on animal studies.<sup>187</sup>

280. Available data on TDA primarily comes from animal studies. These studies strongly support an association between TDA and hepatic cancer.<sup>188</sup> There is evidence of a link between TDA exposure and pulmonary fibrosis based on in vitro studies in which human lung fibroblasts were exposed to TDI and TDA.<sup>189</sup> The EPA has determined that acute exposure to

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<sup>183</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit “76” hereto), at 1 (“[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include ... toluene diamine isomers (TDA)”).

<sup>184</sup> See *Toluene diisocyanates*, IARC Monographs Vol. 71, IARC, available for download at [https://publications.iarc.fr/\\_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf](https://publications.iarc.fr/_publications/media/download/2317/fb198ec8e8f32d0a60294331930c5a04f82cac60.pdf) (last accessed Oct. 3, 2022).

<sup>185</sup> See *Toluene 2,4 diamine*, EPA (Jan. 2000), available at: <https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf> (last accessed Oct. 3, 2022).

<sup>186</sup> [https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/docs/sccs\\_o\\_093.pdf](https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_093.pdf) (last accessed Oct. 3, 2022), at 5.

<sup>187</sup> *2,4-Diaminotoluene*, Report on Carcinogens, NTP, available at: <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/diaminotoluene.pdf> (last accessed Oct. 3, 2022).

<sup>188</sup> *Id.*

<sup>189</sup> It is well established that TDI is converted to TDA through hydrolysis (a reaction caused by exposure to water). See *Current Intelligence Bulletin 53, Toluene Diisocyanate (TDI) and Toluenediamine (TDA): Evidence of Carcinogenicity*, NIOSH Pub. No. 90-101 (Dec. 1989), available at: <https://www.cdc.gov/niosh/docs/90-101/default.html> (last accessed Oct. 3, 2022). Thus, ingested TDI may react with saliva and/or gastrointestinal fluids and convert to TDA. Additionally, there is evidence that inhaled TDI is converted into TDA by reaction with a

TDA can produce severe skin and eye irritation, sometimes leading to permanent blindness, respiratory problems (*e.g.*, asthma), rise in blood pressure, dizziness, convulsions, fainting, and coma.<sup>190</sup> Exposure to TDA can also cause irritation of the skin, nose, and throat, damage to reproductive and neurological systems, eye irritation, dermatitis, ataxia, tachycardia, respiratory depression, stomach gas, hypertension, nausea, vomiting, methemoglobinemia, cyanosis, headache, weakness, exhaustion, dizziness, convulsions, fainting, and coma.<sup>191</sup>

#### 4. Diethylene Glycol Is Toxic To Humans.

281. Diethylene glycol (“DEG”) is a widely used solvent. It is a colorless and odorless liquid with a sweetish taste and has often been a contaminant in consumer products, resulting in numerous epidemics of poisoning. DEG is used in the production of polyester polyurethane foam, and Philips has admitted that DEG is a byproduct of PE-PUR foam degradation.<sup>192</sup>

282. DEG has a historical involvement in mass poisonings around the world. Famously, DEG caused the death of 100 people across 15 states in the 1937 Elixir Sulfanilamide Incident, which served as a catalyst for the enactment of the Federal Food, Drug, and Cosmetic Act (“FDCA”) in 1938.<sup>193</sup>

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substance (glutathione) present in the lungs. As a result, observed effects ascribed to TDI may be due to unmeasured conversion to TDA after exposure.

<sup>190</sup> *Id.*

<sup>191</sup> See *Toluene 2,4 diamine*, EPA (Jan. 2000), available at: <https://www.epa.gov/sites/default/files/2016-09/documents/toluene-2-4-diamine.pdf> (last accessed Oct. 3, 2022).

<sup>192</sup> See Royal Philips Informational PDF, Sleep and Respiratory Care update: Clinical Information (July 8, 2021) (Exhibit “76” hereto), at 1 (“[T]he degradative by-products of a PE-PUR foam after a humid ageing experiment were found to include diethylene glycol (DEG) ....”).

<sup>193</sup> <https://www.fda.gov/files/about%20fda/published/The-Sulfanilamide-Disaster.pdf> (last accessed Oct. 3, 2022).

283. DEG is a toxic substance with a mean fatal dose of 1 mL/kg of pure DEG.<sup>194</sup> Ingesting only a small amount may result in gastrointestinal distress and stupor.<sup>195</sup> Exposure may cause irritation of the eyes, skin, and mucous membranes.<sup>196</sup> DEG has also been shown to have damaging toxic, irritating, and inflammatory properties when inhaled.<sup>197</sup>

##### **5. Dimethyl Diazine Is A Precursor To A Known Carcinogen.**

284. Dimethyl diazene (“DD”), also known as azomethane, is “associated with the production process of the [PE-PUR] foam.”<sup>198</sup> Philips has admitted that DD is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.<sup>199</sup>

285. IARC has not yet evaluated the potential carcinogenicity of DD to humans, as there is scant data concerning the effects of DD on humans and animals. However, DD is a member of a family of carcinogenic substances: 1,2-dimethylhydrazine (a Group 2A probable human carcinogen that exhibits hepatotoxic effects along with injuries to other organs in animal experiments<sup>200</sup>) dehydrogenates into DD, which then oxidizes into azoxymethane (a known

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<sup>194</sup> L.J. Schep, *et al.*, *Diethylene glycol poisoning*, Clin. Toxicol. 47(6):525-35 (July 2009).

<sup>195</sup> See *Ethylene Glycol: Systemic Agent*, NIOSH, available at: [https://www.cdc.gov/niosh/ershdb/emergencyresponsecard\\_29750031.html](https://www.cdc.gov/niosh/ershdb/emergencyresponsecard_29750031.html) (last accessed Oct. 9, 2022).

<sup>196</sup> *Id.*

<sup>197</sup> See, e.g., C.J. Hardy, *et al.*, *Twenty-eight-day repeated-dose inhalation exposure of rats to diethylene glycol monoethyl ether*, Fundam. Appl. Toxicol. 38(2):143-7 (Aug. 1997).

<sup>198</sup> See Royal Philips Informational PDF, *Sleep and Respiratory Care update: Clinical Information* (July 8, 2021) (Exhibit “76” hereto), at 3 (finding that during “testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)”).

<sup>199</sup> *Id.*

<sup>200</sup> G. Choudary, *Toxicological Profile for Hydrazines*, Agency for Toxic Substances and Disease Registry (1997); R.B. Wilson, *Species variation in response to dimethylhydrazine*, *Toxicology and Applied Pharmacology*, 38:3 (1976); M.A. Bedell, *et al.*, *Cell Specificity in Hepatocarcinogenesis: Preferential Accumulation of O6 Methylguanine in Target Cell DNA*

carcinogen that has not yet been classified by the EPA or IARC). Azoxymethane further oxidizes into methylazoxymethanol, a Group 2B possible human carcinogen.<sup>201</sup> Both methylazoxymethanol and 1,2-dimethylhydrazine have been found to metabolize into formaldehyde, a Group 1 known carcinogen.<sup>202</sup> Thus, an individual regularly exposed to DD may also have been exposed to 1,2-dimethylhydrazine, azoxymethane, methylazoxymethanol, and/or formaldehyde—each of which is recognized as a known or probable carcinogen—as these compounds are oxidized and metabolized.

286. DD is clearly linked to colorectal cancer in mice. Azoxymethane, the product of oxidized DD, is used to induce colorectal cancer in animals and has been shown to cause hepatic lesions, intestinal tumors, and renal tumors.<sup>203</sup> Oxidized azoxymethane produces methylazoxymethanol, which is known to cause DNA damage and has been associated with amyotrophic lateral sclerosis, parkinsonism, dementia, colon cancer, liver cancer, and prostate

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during Continuous Exposure of Rats to 1,2-Dimethylhydrazine, *Cancer Res* 42:3079-3083 (1982); W.J. Visek, *et al.*, *Dietary protein and chronic toxicity of 1,2-dimethylhydrazine fed to mice*, *Journal of Toxicology and Environmental Health*, 32:4, 383-413 (1991).

<sup>201</sup> E. Fiala, *Investigations into the metabolism and mode of action of the colon carcinogen 1, 2-dimethylhydrazine*, *Cancer*, 36:2407-12 (Dec. 1975); S. Wolter, N. Frank, *Metabolism of 1,2-dimethylhydrazine in isolated perfused rat liver*, *Chemico-Biological Interactions*, 42:3, 335-344 (1982); IARC Monograph – 71-42, IARC (1987); IARC Monograph Supplement 7, IARC (1987); H. Druckrey, *Production of colonic carcinomas by 1,2-dialkylhydrazines and azoxyalkanes*, *Carcinoma of the Colon and Antecedent Epithelium* 267-279 (1970).

<sup>202</sup> P. Harbach, *et al.*, *Effects of selenium on 1,2-dimethylshydrazine metabolism and DNA alkylation* (1981); S.N. Newaz, *et al.*, *Metabolism of the Carcinogen 1,2Dimethylhydrazine by Isolated Human Colon Microsomes and Human Colon Tumor Cells in Culture* (1983); J. Erikson, *et al.*, *Oxidative Metabolism of Some Hydrazine Derivatives by Rat Liver and Lung Tissue Fractions* (1986).

<sup>203</sup> M. Kobaek-Larsen, *et al.*, *Secondary effects induced by the colon carcinogen azoxymethane in BDIX rats*, *APMIS* 112(6):319-29 (2004 June).

cancer.<sup>204</sup> Exposure to DD—as the precursor to these carcinogenic compounds—means exposure to these other compounds and the health risks they pose.

**6. Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) Is A Toxic Compound.**

287. Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl) (“DTBSBP”) is “associated with the production process of the foam.”<sup>205</sup> According to Philips, DTBSBP is emitted from PE-PUR foam under normal conditions and possibly also as the result of degradation.<sup>206</sup>

288. In 2010, the Canadian government determined that DTBSBP was a Schedule 1 toxic substance under the Canadian Environmental Protection Act “based on available information regarding possible persistence, accumulation in organisms and potential to cause harm to organisms.”<sup>207</sup> These findings prompted Canadian regulators to propose “virtual elimination” of DTBSBP.<sup>208</sup>

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<sup>204</sup> P. Spencer, *et al.*, *Unraveling 50-Year-Old Clues Linking Neurodegeneration and Cancer to Cycad Toxins: Are microRNAs Common Mediators?*, *Frontiers in Genetics* 3 (2012).

<sup>205</sup> See Royal Philips Informational PDF, *Sleep and Respiratory Care Update: Clinical Information* (July 8, 2021) (Exhibit “76” hereto), at 3 (finding that during “testing which ran a device at 35°C ± 2°C for 168 hours, two compounds of concern were emitted from the device: dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)”).

<sup>206</sup> *Id.*

<sup>207</sup> *Phenol, 2,6-bis(1,1-dimethylethyl)-4-(1-methylpropyl)- (DTBSBP)*, Government of Canada, Canada.ca, available at: <https://www.canada.ca/en/health-canada/services/chemical-substances/challenge/batch-8/1-methylpropyl.html>. (last accessed Oct. 3, 2022).

<sup>208</sup> *Id.*

**E. PHILIPS KNEW OF THE DANGERS OF PE-PUR FOAM FOR MANY YEARS PRIOR TO THE RECALL**

289. At the time it installed PE-PUR foam into the Recalled Devices, Philips was required to test the devices in accordance with various international standards, including ISO 18562-2:2017, ISO 18562-3:2017, ISO 10993-13, and ISO 10993-9.

290. At that time, Philips should have known the PE-PUR foam posed a safety risk to users.

291. The FDA concluded after an investigation of Philips' Recalled Devices that beginning in at least 2008, and over time, Philips received hundreds of thousands of customer complaints regarding foam degradation in the Recalled Devices and, years later, received data from a variety of sources confirming foam degradation.

292. The FDA's findings were based, in part, on twenty-one (21) site inspections of Philips' Murrysville, Pennsylvania facility between August 26, 2021 and November 9, 2021. The lead FDA investigator, Katelyn A. Staub-Zamperini, memorialized the agency's findings in a 29-page FDA 483 Report issued on November 9, 2021.<sup>209</sup> The FDA delivered the 483 Report to Rodney Mell, Head of Quality at Philips Respironics, on or around November 9, 2021.<sup>210</sup>

293. A 483 Report "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts."<sup>211</sup> These observations are made in a 483 Report "when in the investigator's judgment, conditions or practices observed

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<sup>209</sup> See generally, 483 Report (Exhibit "5" hereto).

<sup>210</sup> *Id.* at 1, 29.

<sup>211</sup> See FDA Form 483 Frequently Asked Questions (Exhibit "6" hereto).

would indicate that any food, drug, device or cosmetic has been . . . or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.”<sup>212</sup>

294. In connection with the FDA’s investigation for its 483 Report, the FDA learned that Philips received hundreds of thousands of complaints from customers about degradation of the foam in its Recalled Devices beginning at least as early as 2008:

[A] query of your firm’s consumer complaints from 01/01/2008 to current, for the keywords contaminants, particles, foam, debris, airway, particulate, airpath, and black, **resulted in over 222,000 complaints, and over 20,000 of which occurred between 2008 to 2017 and involved Trilogy devices.** Additionally, your firm performed a foam related complaint data analysis in April 2021 on complaints confirmed to be related to or involve foam degradation issues. The raw complaint data documents that **30 Trilogy related complaints were received from 2014 to 2017, and 1,254 related complaints were received across all products containing the affected foam, from 2014 to 2021.**<sup>213</sup>

295. Yet, “[n]o formal investigation, risk analysis, or CAPA were initiated, performed, or documented [by or on behalf of Philips], in response to the at least 222,000 complaints that could potentially be related to foam degradation and received from 2008 to 2017 . . . .”<sup>214</sup>

296. A Corrective and Preventative Action (“CAPA”) refers to procedures that medical device manufactures must follow to identify and attempt to correct a quality problem after one is detected. *See* 21 C.F.R. § 820.100. A CAPA is designed “to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence.”<sup>215</sup>

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<sup>212</sup> *Id.*

<sup>213</sup> 483 Report (Exhibit “5” hereto), at 12 (emphasis added).

<sup>214</sup> *Id.* at 16.

<sup>215</sup> *See Food and Drug Administration, Corrective and Preventative Actions (CAPA)*, <https://www.fda.gov/corrective-and-preventive-actions-capahttps://www.fda.gov/corrective-and-preventive-actions-capa> (last accessed Oct. 3, 2022).

297. The FDA also found that Philips “was made aware of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015 . . . .”<sup>216</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

298. In fact, an adverse event report from the FDA Manufacturer and User Facility Device Experience (“MAUDE”) database shows that, as early as 2011, Philips knew that a patient discovered “black dust” on her nose when she awoke after using a Philips RemStar CPAP device and subsequently underwent treatment for “intoxication” and “chest tightness.”<sup>218</sup>

299. Philips investigated this report and confirmed that the device contained “evidence of an unk[nown] black substance in the air path and on internal components . . . present throughout both the intake and exhaust portions of the air path . . . .”<sup>219</sup>

300. The FDA found that Philips’ analysis of consumer complaints was itself defective in that it “was not adequately performed to identify or detect quality problems.”<sup>220</sup> The FDA concluded that “potential foam degradation in Trilogy ventilator devices is not an isolated incident, and you [Philips] also have not documented a detailed rationale for why harm is not

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<sup>216</sup> 483 Report (Exhibit “5” hereto), at 18.

<sup>217</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

<sup>218</sup> MAUDE Adverse Event Report: RESPIRONICS, INC. REMSTAR PRO INTERNATIONAL, [http://www.fda.com/advanced\\_maude\\_query/324fd08a137ce36c2d5faf453ee26f2f](http://www.fda.com/advanced_maude_query/324fd08a137ce36c2d5faf453ee26f2f) (last accessed Oct. 3, 2022).

<sup>219</sup> *Id.*

<sup>220</sup> 483 Report (Exhibit “5” hereto), at 16.



likely to occur again, as required by your Health Hazard Evaluation’s instructions.”<sup>221</sup> In light of this, the FDA concluded that Philips’ “risk analysis is inadequate or was not performed when appropriate or within an appropriate time frame of your firm becoming aware” of these issues.<sup>222</sup>

301. Company documents show that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

302. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>221</sup> *Id.* at 13.

<sup>222</sup> *Id.* at 3.

<sup>223</sup> [REDACTED]

<sup>224</sup> [REDACTED]

<sup>225</sup> [REDACTED]

<sup>226</sup> [REDACTED]

[REDACTED]

[REDACTED]

303. Indeed, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

304. The FDA has concluded that:

Beginning in 2015, Philips received data from a variety of sources regarding degradation of the PE-PUR foam contained within the recalled devices, including complaints, test reports, information from suppliers, and information from another entity owned by Philips' parent company. Philips failed to adequately evaluate this data and incorporate it into its CAPA [Corrective and Preventive Actions] system for further investigation and potential mitigation, as required by current good manufacturing practice requirements codified in 21 C.F.R. § 820.100.<sup>229</sup>

305. The FDA 483 Report notes that "an incorrect and non-specified polyester polyurethane, raw foam product, sourced from your [Philips'] raw foam supplier resulted in [redacted] non-conforming Trilogy Evo ventilatory finished devices being approved, released, and distributed, which further resulted in the ongoing correction and removal."<sup>230</sup> The correction and removal "were established as part of [Philips'] response to failed VOC and ISO 18562 testing of related Trilogy EVO ventilatory medical devices ... which resulted from the presence

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<sup>227</sup> [REDACTED]

<sup>228</sup> [REDACTED]

<sup>229</sup> 518(b) Notice (Exhibit "72" hereto), at 6.

<sup>230</sup> 483 Report (Exhibit "5" hereto), at 25.

of the non-specified polyester polyurethane foam component, incorrectly supplied by [Philips'] raw foam supplier.”<sup>231</sup>

306. Company documents show that from at least as early as 2016, Royal Philips has demonstrated a systematic level of involvement in and control over testing the PE-PUR foam in the Recalled Devices and investigating the problems with that foam.

307. For example, there is evidence that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

308. In addition, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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<sup>231</sup> *Id.*

<sup>232</sup> [REDACTED]

<sup>233</sup> [REDACTED]

<sup>234</sup> [REDACTED]

[REDACTED]

<sup>235</sup> [REDACTED]

<sup>236</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

309. Philips explains that “Innovation & Strategy advances innovation together with Philips’ businesses, markets and partners. This entails cooperation between research, design, medical affairs, professional services, marketing, strategy and businesses in a multi-disciplinary fashion, from early exploration to first-of-a-kind offerings.”<sup>239</sup> The I&S Hub is also responsible for providing engineering solutions to all of Philips businesses, which is “accountable for bringing engineering capabilities in Philips to world-class level to realize innovations that deliver on our customers’ needs. . . Taking a customer-first approach, Engineering Solutions turns ideas into working innovations by providing deep engineering expertise, cross-business product platforms, and innovation processes and tools. Engineering Solutions also works for selected external companies in the healthcare, high-tech and semiconductor industries.”<sup>240</sup>

310. Additionally, “The role of Innovation & Strategy is to listen to the voice of the customer and, in collaboration with the operating businesses and the markets, direct the company strategy and innovation roadmap to achieve our growth and profitability ambitions. The various

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<sup>237</sup> [REDACTED]  
[REDACTED] *see also* Royal Philips 2020 SEC Form 20-F filing, Exhibit 8 (Exhibit “16” hereto). [REDACTED]  
[REDACTED]

<sup>238</sup> [REDACTED]  
[REDACTED]

<sup>239</sup> *See* Royal Philips 2021 Annual Report (Exhibit “13” hereto), at 21.

<sup>240</sup> *Id.*

components of Innovation & Strategy include: the Chief Technology Office (CTO), Research, HealthSuite Platform, the Chief Medical Office, Engineering Solutions, Experience Design, Healthcare Transformation Services, Strategy, and Partnerships. Our four largest Innovation Hubs are in Eindhoven (Netherlands), Cambridge (USA), Bangalore (India) and Shanghai (China).”<sup>241</sup> While the Hub appears to be centered in Eindhoven, Philips also has employees [REDACTED]

[REDACTED]

311. Later in 2016, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

312. In December 2018, [REDACTED]

[REDACTED]

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<sup>241</sup> *Id.*

<sup>242</sup> [REDACTED]

<sup>243</sup> [REDACTED]

[REDACTED]

<sup>244</sup> [REDACTED]

[REDACTED]

<sup>245</sup> [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

313. In May 2020, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

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246 [REDACTED]

[REDACTED]

247 [REDACTED]

248 [REDACTED]

249 [REDACTED]

[REDACTED]

250 [REDACTED]

251 [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

314. On May 2, 2022, the FDA issued a formal notice to Philips pursuant to Section 518(b) of the FDCA, 21 U.S.C. § 360h(b) (the “518(b) Notice”).<sup>255</sup> The 518(b) Notice stated that the FDA’s “Center for Devices and Radiological Health (CDRH) is proposing that an order should be issued pursuant to section 518(b)” of the FDCA “to require Philips to submit a plan for the repair, replacement, and/or refund of the purchase price of devices subject to the recall that were manufactured after November 2015, sufficient to assure that the unreasonable risk of substantial harm to the public health presented by those devices will be eliminated.”<sup>256</sup> This notice was directed to Thomas J. Fallon, Head of Quality, Sleep and Respiratory Care, for Philips Respironics, Inc.

315. The 518(b) Notice stated that “there is sufficient evidence for FDA to determine that the devices subject to the recall present an unreasonable risk of substantial harm to the

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<sup>252</sup> [REDACTED]

<sup>253</sup> [REDACTED]

<sup>254</sup> [REDACTED]

<sup>255</sup> 518(b) Notice (Exhibit “72” hereto).

<sup>256</sup> *Id.* at 1.

public health” and “that there are reasonable grounds to believe that the recalled devices that Philips manufactured after November 2015 were not properly manufactured with reference to the state of the art as it existed at the time of the devices’ manufacture.”<sup>257</sup>

316. The FDA concluded that “patients and providers cannot readily mitigate the unreasonable risk associated with the recalled devices.”<sup>258</sup>

317. The FDA also concluded that “[t]his risk is not the unavoidable byproduct of current ventilator, CPAP machine, and BiPAP machine technologies. Indeed, Philips and its competitors market ventilators, CPAP machines, and BiPAP machines that do not use PE-PUR foam.”<sup>259</sup>

**1. In 2015, Philips Communicated With Its Foam Suppliers About The Problem Of PE-PUR Foam Degradation.**

318. The PE-PUR foam that Philips used in its Recalled Devices was manufactured by William T. Burnett & Co. (“Burnett”), a bulk foam manufacturer. Burnett produces foam in sheets that are between approximately four feet to more than six feet wide and may be as long as one hundred or two hundred feet.

319. Burnett sells its bulk foam to intermediaries, including PolyTech and The SoundCoat Company (“SoundCoat”). PolyTech and SoundCoat then sell the foam to Philips, either directly or through another intermediary, such as Paramount Die Corporation, which may modify the foam.

320. According to the FDA, “email correspondence between [Philips] and its raw foam supplier [PolyTech] beginning 10/30/2015 and forward, document that [Philips] was made aware

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<sup>257</sup> *Id.* at 2.

<sup>258</sup> *Id.*

<sup>259</sup> *Id.* at 6.



of polyester polyurethane [PE-PUR] foam degradation issues in/around October 2015, which was later confirmed by [Philips'] foam supplier on 08/05/2016, via email.”<sup>260</sup>

321. On August 5, 2016, Bob Marsh, a PolyTech employee, wrote to Lee Lawler,<sup>261</sup> an employee of Burnett, referencing a concern expressed by one of its customers, Philips, in the Fall of 2015 regarding foam degradation in its medical devices.<sup>262</sup> Mr. Marsh stated: “They [Philips] are asking again, and wondered if we could give them any estimate on lifespan of the foam when exposed to 40 C and high humidity.”<sup>263</sup> Mr. Lawler responded that, under those conditions, he “would not be surprised if ester foam . . . would exhibit signs of hydrolysis in as short a time as a year.”<sup>264</sup> He added: “that is not a good environment for polyester foam. Polyether foam could last years in that environment.”<sup>265</sup> Presumably referring to Philips, Mr. Marsh responded that he would “let them know they’d be better off with the ether.”<sup>266</sup> [REDACTED]

[REDACTED]

[REDACTED]

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<sup>260</sup> 483 Report (Exhibit “5” hereto), at 18.

<sup>261</sup> The Affidavit of Lee Lawler, Technical and R&D Manager at Burnett (“Lawler Aff.”), is filed in MDL No. 3014, Case 2:21-mc-01230-JFC, at ECF 589-7, and attached hereto, without exhibits, as Exhibit “94.”

<sup>262</sup> See Email exchange between Bob Marsh at PolyTech and Lee Lawler at Burnett (Lawler Aff. Exh. E) (attached hereto as Exhibit “95”), at WTB 000056.

<sup>263</sup> *Id.*

<sup>264</sup> *Id.*

<sup>265</sup> *Id.*

<sup>266</sup> *Id.*

<sup>267</sup> [REDACTED]

[REDACTED]

[REDACTED]

322. Indeed, [REDACTED]

[REDACTED]

[REDACTED]

323. Knowing about these issues with the PE-PUR foam, Philips tested the foam material used in its Recalled Devices. According to the FDA, “this testing spoke only to the limited finding that in the case of the [redacted] foam samples ‘returned from service in a Pacific rim location,’ spectroscopy results were ‘consistent with an environmental/chemical exposure causing base polymer cleavage and embrittlement of the material.’”<sup>269</sup> Nonetheless, based on the results of this limited testing, Philips concluded that no escalation to a CAPA process was required.<sup>270</sup>

324. According to the FDA, “no further investigation, health hazard evaluation, risk analysis, or design review was performed or documented by Philips at that time . . . and no preventative maintenance procedures were implemented,” other than a limited “preventative maintenance procedure” instituted by a Philips “entity owned by the parent company of Philips Respironics . . . to replace the air intake assembly of Trilogy ventilator products, due to complaints that had been received regarding degradation of the PE-PUR foam contained in the products.”<sup>271</sup> And even then, “Philips did not verify the effectiveness of this measure.”<sup>272</sup>

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<sup>268</sup> [REDACTED]

<sup>269</sup> 518(b) Notice (Exhibit “72” hereto), at 7.

<sup>270</sup> *Id.*

<sup>271</sup> *Id.* at 6-7.

<sup>272</sup> *Id.* at 8.

325. As Philips continued to ask its supplier about the properties of the PE-PUR foam and encountered more warning signs, it continued to put that foam in medical devices that millions of its customers were breathing through daily.

326. Testing conducted for Philips in 2016 confirmed that Mr. Lawler from Burnett was correct. According to the FDA, this testing “determined that the PE-PUR foam was susceptible to degradation, resulting in the conclusion at that time that ‘polyester urethanes show bad resistance against high humidity in combination with high temperature.’”<sup>273</sup> Additional testing “determined that, compared to PE-PUR foam, another type of foam, polyether urethane, ‘show[s] a far better resistance against high humidity at high temperature.’”<sup>274</sup>

327. The 483 Report identified “at least fourteen instances, assessments, and/or test reports, dated from 04/01/2016 to 01/22/2021, where [Philips] was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices.”<sup>275</sup> It listed the specific analyses and tests, including one which concluded that “contrary to polyester urethane foams, [redacted] foams shows a far better resistance against high humidity at high temperature.”<sup>276</sup>

328. Philips received at least 110 complaints confirmed to be related to foam degradation between 2014 and 2017.<sup>277</sup> Approximately 80 of these complaints concerned CPAP and BiPAP devices.<sup>278</sup>

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<sup>273</sup> *Id.* at 7-8.

<sup>274</sup> *Id.* at 8.

<sup>275</sup> 483 Report (Exhibit “5” hereto), at 3.

<sup>276</sup> *Id.* at 4.

<sup>277</sup> 518(b) Notice (Exhibit “72” hereto), at 7.

<sup>278</sup> *Id.* at 8.

329. Nonetheless, Philips continued manufacturing and selling the now Recalled Devices containing PE-PUR foam and failed to warn prescribing physicians, durable medical equipment companies and the patient consumers of this problem.

**2. Philips Opened An Internal Investigation Into Foam Degradation In Mid-2018 That Confirmed PE-PUR Foam Is Prone To Degradation.**

330. In April 2018, Philips opened a precursor to a formal CAPA, referred to by Philips as a CAPA INV 0988, “to investigate complaints related to potential foam degradation for the Trilogy devices in Australia and to determine what actions should be taken.”<sup>279</sup> Philips reported that “[u]nits were returned from the field where the Trilogy Removable Air Path Foam [redacted] and the foam in the Inlet Air Path Assembly [redacted] was degrading, and getting into the motor/air path, causing at least 1 Trilogy unit to fail.”<sup>280</sup>

331. On April 20, 2018, Vincent Testa, a Project Mechanical Engineer at Philips RS, emailed Bonnie Peterson, a Project Manager at PolyTech. Mr. Testa stated, “We use the PAFS foam in the air path of our Trilogy family of ventilators as a means for noise reduction . . . .”<sup>281</sup>

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<sup>279</sup> *Id.*



<sup>280</sup> 483 Report (Exhibit “5” hereto), at 14.

<sup>281</sup> *See* Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (attached hereto as Exhibit “98”), at WTB 000070.

PAFS foam is PolyTech’s open cell, flexible acoustical grade PE-PUR foam.<sup>282</sup> Mr. Testa at Philips continued: “Recently weve [*sic*] received a few complaints from our customers that the foam is disintegrating . . . . The material sheds and is pulled into the ventilator air path. As you can imagine, this is not a good situation for our users.”<sup>283</sup> Mr. Testa asked, “what could cause this material to break down.”<sup>284</sup>

332. On April 23, 2018, Mr. Marsh from PolyTech forwarded Philips’ April 20, 2018 email to Mr. Lawler from Burnett, reporting that “[t]he customer [Philips] is finding degradation of the ester foam and the urethane film in their device, such that particles are breaking off and flowing in the airstream.”<sup>285</sup>

333. On May 2, 2018, Mr. Marsh added in an email to Mr. Lawler that “Philips gave us another bit of information. They tested ether vs ester in high heat and humidity and found ether to be the better performer. It validated what we (you) had conveyed.”<sup>286</sup> Mr. Marsh asked whether exposure to oxygen, higher temperature, and higher humidity could accelerate deterioration of PE-PUR foam.<sup>287</sup>

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<sup>282</sup> See PolyTech website, <https://www.polytechinc.com/products/acoustic-foamhttps://www.polytechinc.com/products/acoustic-foam> (last accessed Oct. 3, 2022).

<sup>283</sup> See Email from Vincent Testa at Philips to Bonnie Peterson at PolyTech (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000070.

<sup>284</sup> *Id.*

<sup>285</sup> See Email from Bob Marsh to Lee Lawler dated 4/23/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000069-70.

<sup>286</sup> See Email from Bob Marsh to Lee Lawler dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000069.

<sup>287</sup> *Id.*

334. Mr. Lawler responded that he did “not believe that exposure to oxygen will cause any significant damage to polyurethane foam unless elevated temperature and/or humidity is also present.”<sup>288</sup>

335. On May 3, 2018, Mr. Testa from Philips admitted in a follow-up email to Mr. Marsh from PolyTech, that:

We [Philips] are evaluating our options regarding the foam. We could switch to the PAF [ether-based foam], or we could indicate a preventative maintenance cycle in which they would replace the PAFS [ester-based] foam pieces. . . . The environmental conditions for our device are a maximum of 40C and 95% R.H. Note the difference in temperature.<sup>289</sup>

336. Mr. Testa at Philips asked Mr. Marsh from PolyTech the following:

1. Please ask your foam supplier to calculate the service life based on this higher temperature (40C vs. 27C).

a. It would also be useful if they could provide a graph depicting failure over time. For example, if tensile strength reduced over time, they would plot strength vs. time.

2. At the end of the service life, what is the failure mode of this material?<sup>290</sup>

337. Mr. Marsh again forwarded these questions to Mr. Lawler at Burnett, who responded:

I am unable to answer Question Number 1. We would not recommend using **polyester** foam in such an environment and have no direct data to use to calculate the rate of hydrolysis. **Polyether** foam lifetime would not be expected to reduce significantly at the stated conditions. Use with pure oxygen could shorten the lifetime some by promoting more rapid oxidation. I do not know the extent of the reduction, but do not expect it to be overly significant.

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<sup>288</sup> See Email from Lee Lawler to Bob Marsh dated 5/2/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000069.

<sup>289</sup> See Email from Vincent Testa to Bob Marsh dated 5/3/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000068-69).

<sup>290</sup> *Id.*

Polyester foam will lose tensile strength and overall integrity as it hydrolyzes. It will eventually decompose to a sticky powder. That will happen very rapidly at 40C, 95% R.H.<sup>291</sup>

338. Mr. Lawler from Burnett added: “Is it one of our data sheets that states foam lifetime being 10 years at 95% R.H? I do not think I have seen a sheet with that statement.”<sup>292</sup> Mr. Marsh at PolyTech responded that he would pass along the information to Philips and that “[w]e have no idea where that statement came from. It has been on our data sheets for probably 20 years. We are removing it.”<sup>293</sup>

339. On May 23, 2018, Mr. Marsh from PolyTech forwarded to Mr. Lawler from Burnett another question from Mr. Testa at Philips, about the degradation of the foam it was using in its Recalled Devices.<sup>294</sup> Mr. Testa explained that Philips had “sent samples to a local lab for analysis.”<sup>295</sup> The local lab concluded that the degradation was a result of cleavage of the bonds in the base polymer, and Mr. Testa stated that “[f]urther investigation concluded that prolonged exposure to high humidity causes the foam to degrade.”<sup>296</sup> Mr. Testa noted that “[a]s

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<sup>291</sup> See Email from Lee Lawler to Bob Marsh dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000067-68 (emphasis in original).

<sup>292</sup> *Id.* at WTB 000068.

<sup>293</sup> See Email from Bob Marsh at PolyTech to Lee Lawler at Burnett dated 5/4/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000067. Notably, PolyTech still advertises on its website that PE-PUR foam is resistant to heat and humidity. See PolyTech “Acoustic Foam for Sound Adsorption” webpage, <https://www.polytechinc.com/products/polymer-acoustic-foam> (last accessed Oct. 7, 2022) (“Ester foams have superior physical properties and offer excellent resistance to heat, moisture, and chemicals.”) (attached hereto as Exhibit “99”).

<sup>294</sup> See Email from Bob Marsh to Lee Lawler dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000066-67.

<sup>295</sup> *Id.* at WTB 000066.

<sup>296</sup> *Id.* at WTB 000067.

the foam degrades it breaks down into small particulate” and asked whether the foam “maintain[s] its UL 94 Flame Resistance rating if it is broken down into particulate?”<sup>297</sup>

340. Mr. Lawler replied: “I am sure the degraded foam will not perform well in UL94 testing, though I cannot imagine how one would actually perform the test on such degraded material.”<sup>298</sup>

341. On June 7, 2018, Mr. Testa at Philips again emailed Mr. Marsh at PolyTech:

As we continue our investigation of the deterioration of the PAFS foam, a few questions has [*sic*] been posed regarding the material. Can you please reach out to your foam supplier regarding the following.

1. What is the actual composition of the polyurethane-ester foam PAFS-038? (CAS #s/percentages/weight percent/reactive groups etc. any chemistry is very appreciated)
2. What kind of diisocyanate is used in the polyurethane foam synthesis process and how much?
3. Is diethylene glycol or another polyol utilized in the foam synthesis process?
4. Have you tested to see if all diisocyanate groups are reacted in your foam or are there unreacted groups even after manufacturing?<sup>299</sup>

342. Mr. Marsh (PolyTech) forwarded the questions to Mr. Lawler (Burnett), who asked why Mr. Testa (Philips) needed this information. Mr. Marsh did not provide a definitive answer but said, “What Vince [Testa] told us is that they are investigating alternatives to

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<sup>297</sup> *Id.*

<sup>298</sup> See Email from Lee Lawler to Bob Marsh dated 5/23/2018 (Lawler Aff. Exh. H) (Exhibit “98” hereto), at WTB 000066.

<sup>299</sup> See Email from Vincent Testa to Bob Marsh dated 6/7/2018 (Lawler Aff. Exh. I) (attached hereto as Exhibit “100”), at WTB 000076-77.



polyurethane foam (ester and ether).”<sup>300</sup> Mr. Lawler ultimately did not answer Mr. Testa’s questions because they touched on Burnett’s confidential, proprietary information.

343. On June 20, 2018, Philips closed CAPA INV 0988.<sup>301</sup> According to the FDA, Philips implemented “a preventative maintenance procedure for Trilogy devices, but Philips did not verify the effectiveness of this measure.”<sup>302</sup> Yet, “after CAPA INV 0988, Philips modified its CAPA procedures to include ‘requirements to help ensure that CAPAs are fully complete [and] appropriately scoped,’ and that ‘processing the issue [that was the subject of CAPA INV 0988] through the current CAPA program would have result[ed] in an appropriate horizontal assessment.’”<sup>303</sup>

344. The FDA pointed out that Philips’ informal CAPA INV<sup>304</sup> related to these Trilogy devices did “not include, investigate, or examine all of [Philips’] CPAP and BiPAP medical devices, which also include similar air path assemblies and/or the affected polyester polyurethane [PE-PUR] foam, which is susceptible to degradation.”<sup>305</sup> But Philips had acknowledged to the FDA that it had “received approximately eighty complaints related to foam degradation, **on non-Trilogy ventilator devices**, from 2014 to 2017.”<sup>306</sup>

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<sup>300</sup> See Email from Bob Marsh to Lee Lawler dated 6/14/2018 (Lawler Aff. Exh. I) (Exhibit “100” hereto), at WTB 000075.

<sup>301</sup> 483 Report (Exhibit “5” hereto), at 15.

<sup>302</sup> 518(b) Notice (Exhibit “72” hereto), at 8.

<sup>303</sup> *Id.*

<sup>304</sup> The 483 Report explained that Philips’ practice at the time was to first open CAPA requests—called “CAPA INVs”—as a precursor to a formal CAPA, but this could only occur if approved by a “CAPA Review Board” or delegate. See 483 Report (Exhibit “5” hereto), at 14-15.

<sup>305</sup> *Id.* at 15.

<sup>306</sup> *Id.* at 16 (emphasis added).

345. The FDA concluded that Philips had not “adequately established” a process for initiating CAPA procedures.<sup>307</sup> Specifically, the FDA faulted Philips for not initiating a “formal” CAPA after receiving “various complaints alleging foam degradation in Trilogy ventilator devices” and then closing its informal investigation just two months later without “verify[ing] the effectiveness” of the limited “preventative maintenance procedure for Trilogy devices.”<sup>308</sup>

346. Philips continued to receive more information suggesting that the PE-PUR foam was prone to degradation. According to the FDA, “[a] follow-up email amongst [Philips’] personnel, dated 08/24/2018, states that testing confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints . . . .”<sup>309</sup>

347. Further, “[o]n December 12, 2018, several months after CAPA INV 0988 was closed, a report from additional testing conducted for Philips found that ‘[p]olyester polyurethane foam showed clear disintegration after 2 weeks.’”<sup>310</sup>

348. Nonetheless, Philips continued manufacturing and selling the Recalled Devices containing PE-PUR foam.

349. Philips failed to apprise the FDA of the facts and problems it learned from its foam suppliers about premature foam degradation risks.

350. Philips failed to apprise the FDA of consumer, medical provider and durable medical equipment company reports of the presence of foam particles and other device failures.

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<sup>307</sup> *Id.* at 14.

<sup>308</sup> 518(b) Notice (Exhibit “72” hereto), at 8.

<sup>309</sup> 483 Report (Exhibit “5” hereto), at 18.

<sup>310</sup> 518(b) Notice (Exhibit “72” hereto), at 8.

**3. Philips Finally Opened A Formal CAPA In 2019 – But Did Not Initiate A Recall For Two More Years.**

351. In April 2019, Philips received two complaints that “sound abatement foam ‘is degrading and entering the air path.’”<sup>311</sup>

352. In response, in June 2019, Philips finally initiated a formal CAPA, numbered CAPA 7211, related to the issues associated with the PE-PUR foam. But as the FDA explains:

Even then, that CAPA failed to evaluate all relevant data. Philips’ search of FDA’s Manufacturer and User Facility Device Experience (MAUDE) database in connection with CAPA 7211 identified only three medical device reports (MDRs) associated with potential foam degradation involving Trilogy ventilators between January 2011 and January 2021. Yet an MDR analysis conducted by Philips in 2018 had already identified 17 documented complaints related to foam degradation in Trilogy ventilators, and at least 14 of those 17 complaints had related MDRs. Similarly, Philips’ analysis of foam degradation-related complaints conducted in connection with CAPA 7211 identified 1,254 complaints confirmed to be related to foam degradation between 2014 and April 2021 across all affected products, yet this analysis failed to include several complaints confirmed to be related to foam degradation in Trilogy ventilators that were documented in 2018 in connection with CAPA INV 0988.<sup>312</sup>

353. Philips continued to test the PE-PUR foam while the CAPA was underway. A Biological Risk Assessment dated July 2, 2020, found that “the biological and toxicological risks from exposure to degraded PE-PUR foam are of concern....”<sup>313</sup>

354. Another internal “Biological Risk Assessment” dated December 10, 2020 – and “conducted as a result of field reports/complaints regarding degraded sound abatement foam in

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<sup>311</sup> *Id.*

<sup>312</sup> *Id.* at 8-9.

<sup>313</sup> 483 Report (Exhibit “5” hereto), at 7 (“Philips Respironics Inc. (PRI) was made aware in May 2019 that four CPAP units were returned to a service center with degraded sound abatement foam.”) (quoting July 2, 2020 Biological Risk Assessment).

various CPAP and ventilator products”<sup>314</sup> – described the risks that degraded polyurethane foam posed to humans in no uncertain terms:

The cytotoxicity and positive genotoxicity results observed from degraded PE-PUR foam samples **indicate a potential patient risk. Potential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.** Overall, based on an understanding of the toxicological significance of the foam degradants and the results of the ISO 10993 testing to include mutagenic responses in both a bacterial and mammalian system, **the degraded PE-PUR foam is not considered biocompatible and presents a significant biological risk to those patient populations who are exposed to degraded PE-PUR foam.**<sup>315</sup>

355. An additional Philips’ Biocompatibility Risk Assessment dated January 11, 2021, concurred that degraded PE-PUR foam “presents a significant biological risk to patients,” and admitted that “[p]otential cytotoxicity and genotoxicity leading to carcinogenicity are possible outcomes from degraded PE-PUR foam exposure.”<sup>316</sup>

356. Ultimately, in CAPA 7211, Philips concluded that “the cause of the foam degradation condition is long-term exposure to environmental conditions of high temperature combined with high humidity” and reiterated that “the cause of degradation was due to chemical breakdown of the foam due to exposure to water caused by long-term exposure to environmental conditions.”<sup>317</sup>

357. Based on its investigation, the FDA concluded that Philips’ upper management was aware of the foam degradation issues, discussed it at numerous management review meetings, and yet delayed doing anything to rectify or mitigate the hazards:

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<sup>314</sup> *Id.* at 8-9.

<sup>315</sup> *Id.* at 7-8 (emphasis added).

<sup>316</sup> *Id.* at 8.

<sup>317</sup> 518(b) Notice (Exhibit “72” hereto), at 10.

[F]irm management, including management with executive responsibility, were aware of potential foam degradation issues concerning CPAPs, BiPAPs, and Trilogy ventilators since at least 01/31/2020, or earlier, and implemented no further corrective actions until April 2021.

Polyester polyurethane foam degradation issues concerning CPAPs, BiPAPs, and Trilogy Ventilators were discussed at all [redacted] management review meetings, since the 2019 [redacted], dated 01/31/2020 . . . . Additionally, your firm [Philips] became aware of this issue and related field complaints in at least 2015 or earlier.<sup>318</sup>

**F. PHILIPS CONSISTENTLY MARKETING ITS BREATHING MACHINES AS SAFE AND EFFECTIVE EVEN WHEN IT KNEW OF THE PROBLEMS WITH PE-PUR FOAM DEGRADATION AND ASSOCIATED HEALTH RISKS.**

**1. Philips Never Hinted at the Dangerous Condition of the Recalled Devices.**

358. At no point prior to April 2021, when Philips first disclosed foam issues to its shareholders, did Philips even hint that there was a dangerous condition in its recalled CPAP, BiPAP, and ventilator devices. Instead, Philips held itself out as a trusted brand and “global leader in the sleep and respiratory markets.”<sup>319</sup> Its branding promises consumers that they will “[b]reath easier, sleep more naturally.”<sup>320</sup> Philips further assures consumers that its “sleep therapy systems are designed with the needs of care practitioners and patients in mind,” and that its “quality systems reflect [Philips’] commitment to providing enhanced patient comfort,” among

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<sup>318</sup> 483 Report (Exhibit “5” hereto), at 24.

<sup>319</sup> See Philips Respironics website – About Philips Respironics, [http://www.respironics.com/product\\_library](http://www.respironics.com/product_library) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “101”).

<sup>320</sup> *Id.*

other things.<sup>321</sup> And it has long advertised its CPAP and BiPAP Machines as “clinically proven” treatment for sleep disorders.<sup>322</sup>

359. Philips boasts that it has the “most prescribed CPAP systems by U.S. sleep physicians.”<sup>323</sup> The CPAP and BiPAP machines routinely cost from seven or eight hundred dollars to thousands of dollars per machine, and the ventilators cost more than several thousands of dollars per machine.

**2. Philips Knew Some of its Customers Were Using the SoClean Ozone Cleaning Technology with its Devices and Assented to Such Use.**

360. Philips was fully cognizant that many users were utilizing the So-Clean Ozone product in conjunction with its device.

361. For example, on March 6, 2020, in a letter responding to a customer’s request for written guidance, Philips Respironics said using SoClean on its DreamStation will not automatically void the warranty, but the company “reserves the right to void a warranty if it is determined that the use of SoClean caused a defect for which a device otherwise under warranty was returned.”<sup>324</sup> The company said in a statement to HME News that it “does not formally validate the use of SoClean with the DreamStation, but as of Jan. 6, Philips has not denied a warranty claim associated with the use of SoClean with a DreamStation.”<sup>325</sup> Philips told HME

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<sup>321</sup> See <https://www.usa.philips.com/healthcare/solutions/sleep/sleep-therapy> (last accessed Oct. 3, 2022) (Exhibit “102” hereto).

<sup>322</sup> *Id.*

<sup>323</sup> *Id.*

<sup>324</sup> *Business News For Home Medical Equipment Providers* (March 6, 2020), at <https://www.hmenews.com/article/cpap-manufacturers-address-certain-cleaning-devices> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “103”).

<sup>325</sup> *Id.*

News it wrote the letter “to limit confusion and misinformation.”<sup>326</sup> The article in HME News further quoted Philips stating that “Philips is in communication with SoClean to further analyze the potential compatibility of the SoClean with DreamStation therapy devices, and will provide further information as it becomes available,” the company told HME News.<sup>327</sup>

362. By virtue of that communication to a trade journal, Philips not only acknowledged its awareness of the use of the product, but also acknowledged it received warranty complaints amongst users of the DreamStation who also used SoClean, and honored the warranties and communicated with SoClean.

363. Additional evidence that Philips was aware that SoClean was selling a product specifically designed to be used in conjunction with the DreamStation is the website of CPAPDIRECT.COM, a major internet provider of CPAP machines and related paraphernalia which advertised an express adapter kit for So Clean and Dream Station products.<sup>328</sup> Similarly numerous other internet and durable medical equipment companies and retail suppliers of Philips CPAP devices also sold SoClean to be used in conjunction with the Devices, and Philips expressly and impliedly was aware of this combined use.

364. Given that Philips was on notice since at least 2008 of a foam degradation concern, and was also aware of the combined use of its Devices with SoClean, to the extent there is any validity to Philips recent claims attributing foam degradation to SoClean ozone treatment, Philips should have and could have made the same attributions and affirmatively stepped up to

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<sup>326</sup> *Id.*

<sup>327</sup> *Id.*

<sup>328</sup> See CPAP Direct Products Page – SoClean Respiroics System One & DreamStation Adapter, <https://www.cpapdirect.com/cleaning/soclean-respiroics-system-one-and-dreamstation-adapter> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “104”).

expressly warn medical providers, Durable Medical Equipment companies and patients against the combined use of the products in allegedly contributing to premature foam degradation.

365. Instead, recognizing that SoClean consumers seemingly liked having this additional cleaning modality, Philips declined to dissuade patients and customers from the combined use due to a concern that they would lose business to alternative CPAP manufacturers who also tacitly or expressly condoned such joint use.

**3. Philips Sold Its Humidifier Accessory Allowing Warm Storage Conditions and Contributing to Humidity of the Foam.**

366. Philips sold humidifiers to accompany its CPAP devices,<sup>329</sup> especially the DreamStation, stating in the humidifier's User Manual under the heading "Intended Use": "The DreamStation Heated Humidifier is an accessory for the Philips Respironics DreamStation therapy devices to provide moisture to the patient circuit."<sup>330</sup>

367. The humidifier manual quoted above had, under the heading "DreamStation Heated Humidifier Specifications" had environmental specifications that included an "Operating Temperature: 5° to 35° C (41° to 95° F)" as well as "Storage Temperature: -20° to 60° C (-4° to 140° F)" and "Relative Humidity (operating & storage): 15 to 95% (non-condensing)."<sup>331</sup>

368. Philips provided the humidifier option explaining in the DreamStation User Manual that "[y]ou can use the heated humidifier and the heated tube with your device. They are

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<sup>329</sup> Philips' humidifiers are not compatible with CPAP devices manufactured by other companies like ResMed.

<sup>330</sup> See DreamStation Humidifier User Manual, [https://www.documents.philips.com/doclib/enc/11410694/DreamStation\\_Humidifier\\_User\\_Manual.pdf](https://www.documents.philips.com/doclib/enc/11410694/DreamStation_Humidifier_User_Manual.pdf), at 1 (last accessed Oct. 3, 2022) (attached hereto as Exhibit "105").

<sup>331</sup> *Id.* at 12.



available from your home care provider. A humidifier may reduce nasal dryness and irritation by adding moisture to the airflow.”<sup>332</sup>

369. Philips not only knew but recommended the use of the humidifier, and also advised that the device could be stored in a room as warm as 140° F despite their knowledge that warm, hot and humid conditions contributed to rapid degradation of its sound insulating foam.

370. The vast majority of DreamStation patients use the Philips humidifier with their devices.

**G. PHILIPS FINALLY RECALLED ITS DEFECTIVE DEVICES CONTAINING HAZARDOUS PE-PUR FOAM, BUT ONLY AFTER LAUNCHING ITS NEWEST DEVICE WITHOUT PE-PUR FOAM.**

**1. Prior to the Recall, In April And May 2021, Philips Launched The DreamStation 2 (Which Does Not Contain PE-PUR Foam).**

371. Two months prior to the Recall, Philips announced on April 13, 2021, that it was launching the DreamStation 2, a next-generation machine in its DreamStation product family. The DreamStation 2 does not contain PE-PUR foam.

372. Less than two weeks after its launch of the DreamStation 2, on April 26, 2021, Philips announced that its previous generation of DreamStation products and other Recalled Devices posed serious health risks to users. In the same release, Philips tried to convince consumers to purchase and use its new DreamStation 2 device:

Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips’ sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone,\* and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips’ recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips

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<sup>332</sup> See, e.g., DreamStation User Manual (Exhibit “47” hereto), at 22.

is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks. Given the estimated scope of the intended precautionary actions on the installed base, Philips has taken a provision of EUR 250 million.<sup>333</sup>

373. Even when making this announcement, Royal Philips downplayed the significance of the problem claiming “the occurrence rate is very, very low.”<sup>334</sup> At the same time, Royal Philips assured its shareholders that any adverse impact on sales due to the safety risks posed by the Recalled Devices was minimized by introduction of the DreamStation 2: “The good thing is, is that we have launched DreamStations 2.”<sup>335</sup>

**2. Testing Continued To Confirm The Recalled Devices Were Defective and the FDA Received Additional MDRs.**

374. Even as it launched the DreamStation 2 device and announced publicly that its previous generation DreamStation products posed serious health risks to users, Philips continued to conduct tests that confirmed some of its breathing products were defective.

375. For example, on May 17, 2021, Ken Cole from RJ Lee, an industrial forensics analytical laboratory and scientific consulting firm, produced a presentation analyzing the foam in Philips’ Trilogy EVO devices. The presentation states that the investigation was “prompted by staff observation of color variance across both current production and previous builds.”<sup>336</sup>

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<sup>333</sup> See Royal Philips announces its 2021 First-Quarter Results (Apr. 26, 2021), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html> (last accessed Oct. 9, 2022) (attached hereto as Exhibit “106”).

<sup>334</sup> Transcript of Koninklijke Philips NV Earnings Call for First Quarter 2021 Results (April 26, 2021), Fair Disclosure Wire (attached hereto as Exhibit “107”).

<sup>335</sup> *Id.*

<sup>336</sup> See RJ Lee Analysis Review of Trilogy EVO Foam (Lawler Aff. Exh. A) (WTB000001-14) (attached as Exhibit “108” hereto), at WTB000003.

376. The analysis involved six samples of foam, two from units built in 2018 and four taken from Philips' current production stock in May 2021.<sup>337</sup> Some of the samples from 2021 showed "differing cell structure" which is an "[i]ndication of poor process control."<sup>338</sup> The 2021 foam had "significant contaminants."<sup>339</sup> The foam was supposed to be ether-based,<sup>340</sup> but testing revealed indications that some of the foam was actually ester-based.<sup>341</sup>

377. In addition, MDRs associated with the PE-PUR foam breakdown increased significantly.<sup>342</sup> From 2011 to April 2021 when Philips first notified the FDA of their intention to conduct a field action due to concerns pertaining to foam degradation (breakdown) in certain ventilators, BiPAP machines, and CPAP machines, Philips submitted only 30 MDRs that they identified as associated with the PE-PUR foam breakdown and there were no reports of patient injury or death among those 30 MDRs.<sup>343</sup> Eight of those reports were from the United States.

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<sup>337</sup> *Id.* at WTB 000006.

<sup>338</sup> *Id.* at WTB 000008.

<sup>339</sup> *Id.* at WTB 000009; *see also* WTB 000010 ("Indication of poor process control and/or contamination.").

<sup>340</sup> *Id.* at WTB 000002.

<sup>341</sup> *Id.* at WTB 000013.

<sup>342</sup> As stated above, manufacturers, such as Philips, are required to submit medical device reports (MDRs) when information reasonably suggests that their device may have caused or contributed to a death or serious injury, or has malfunctioned, and that device or a similar device they manufacture would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. Health professionals, consumers, and patients may voluntarily submit reports of device adverse events and malfunctions to the FDA. *See, e.g.*, 21 C.F.R. § 803.20.

<sup>343</sup> The FDA's latest information about medical device reports (MDRs) associated with the Recalled Devices on August 16, 2022 is available here: [https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due?utm\\_medium=email&utm\\_source=govdelivery#mdr](https://www.fda.gov/medical-devices/safety-communications/update-certain-philips-respironics-ventilators-bipap-machines-and-cpap-machines-recalled-due?utm_medium=email&utm_source=govdelivery#mdr) (last accessed Oct. 3, 2022) ("FDA MDR Update").

378. After Philips notified the FDA of its intention to conduct a field action in April 2021 through July 31, 2022, the amount of MDRs the FDA received increased significantly as did the “reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.”<sup>344</sup> Specifically, the FDA reported:

- From April 2021 through April 30, 2022, the FDA received more than 21,000 MDRs, including 124 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.
- From May 1, 2022, through July 31, 2022, the FDA received more than 48,000 MDRs, including 44 reports of death, associated with the PE-PUR foam breakdown or suspected foam breakdown.

379. The FDA continued: “A wide range of injuries have been reported in these MDRs, including cancer, pneumonia, asthma, other respiratory problems, infection, headache, cough, dyspnea (difficulty breathing), dizziness, nodules, and chest pain.”<sup>345</sup>

### **3. Finally, In June 2021, Philips Recalled Its Defective Devices.**

380. Finally, on June 14, 2021, Royal Philips issued a press release announcing a recall notice directed to its customers in the United States, and a field safety notice for the rest of the world, stating:

To date, Philips has produced millions of Bi-Level PAP, CPAP and mechanical ventilator devices using the PE-PUR sound abatement foam. Despite a low complaint rate (0.03% in 2020), Philips determined based on testing that there are possible risks to users related to this type of foam. The risks include that the PE-PUR foam may degrade into particles which may enter the device’s air pathway and be ingested or inhaled by the user, and the foam may off-gas certain chemicals. The foam degradation may be exacerbated by use of unapproved cleaning methods, such as ozone, and high heat and high humidity environments may also contribute to foam degradation.

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<sup>344</sup> *Id.* (stating “The MDRs received included both mandatory reports from Philips and voluntary reports from health professionals, consumers, and patients.”).

<sup>345</sup> *Id.*

Therefore, Philips has decided to voluntarily issue a recall notification to inform patients and customers of potential impacts on patient health and clinical use related to this issue, as well as instructions on actions to be taken.<sup>346</sup>

381. Philips stated that “[t]he majority of the affected devices within the advised 5-year service life are in the first-generation DreamStation product family.”<sup>347</sup> Philips elaborated:

Based on the latest analysis of potential health risks and out of an abundance of caution, the recall notification advises patients and customers to take the following actions:

- For patients using affected BiLevel PAP and CPAP devices: Discontinue use of your device and work with your physician or Durable Medical Equipment (DME) provider to determine the most appropriate options for continued treatment. To continue use of your device due to lack of alternatives, consult with your physician to determine if the benefit of continuing therapy with your device outweighs the risks identified in the recall notification.
- For patients using affected life-sustaining mechanical ventilator devices: Do not stop or alter your prescribed therapy until you have talked to your physician. Philips recognizes that alternate ventilator options for therapy may not exist or may be severely limited for patients who require a ventilator for life-sustaining therapy, or in cases where therapy disruption is unacceptable. In these situations, and at the discretion of the treating clinical team, the benefit of continued usage of these ventilator devices may outweigh the risks identified in the recall notification.

### **Possible health risks**

The company continues to monitor reports of potential safety issues as required by medical device regulations and laws in the markets in which it operates. To date, there have been no reports of death as a result of these issues. Philips has received reports of possible patient impact due to foam degradation. The potential risks of particulate exposure include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects. The potential risks of chemical exposure due to off-gassing include headache, irritation, hypersensitivity, nausea/vomiting, and possible toxic and carcinogenic effects.

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<sup>346</sup> Royal Philips Press Release, Philips issues recall notification\* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit “34” hereto) (asterisks and footnotes omitted).

<sup>347</sup> *Id.*

Philips has received no reports regarding patient impact related to chemical emissions.<sup>348</sup>

382. Corroborating the dangerous nature of the Recalled Devices, on July 22, 2021, the FDA upgraded Philips' recall of the Recalled Devices to its most serious classification, Class I, which according to the FDA means: "A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death."<sup>349</sup>

383. Philips' Recall announcement instructed users to not use the Recalled Devices because of the health risks. This confirmed the true nature of the recalled products, which at all times were adulterated and worthless.

384. Philips took similar action with respect to its defective CPAP, BiPAP, and ventilator devices across the globe.

385. Shortly after Philips' recall announcement, Philips' main competitor, ResMed, issued a message regarding the recall, stating that "ResMed devices are not subject to this recall and are safe for patients to use. ResMed devices use a different material for sound reduction than the material used by the other manufacturer."<sup>350</sup>

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<sup>348</sup> *Id.* (asterisks and footnotes omitted).

<sup>349</sup> See FDA – Recalls Background and Definitions, <https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "109").

<sup>350</sup> See ResMed webpage, Information regarding a separate manufacturer's product recall (June 2021), archived at: [https://web.archive.org/web/20210617041516mp\\_/https://www.resmed.com/en-us/other-manufacturer-recall-2021/](https://web.archive.org/web/20210617041516mp_/https://www.resmed.com/en-us/other-manufacturer-recall-2021/) (last accessed Oct. 7, 2022) (attached hereto as Exhibit "110").

386. ResMed devices and ventilators use polyether polyurethane or silicone-based foam, not PE-PUR foam, for sound abatement purposes.<sup>351</sup>

**H. THE MEASURES TAKEN BY PHILIPS, AND BY ROYAL PHILIPS IN PARTICULAR, TO RECALL AND REPLACE THE DEFECTIVE DEVICES HAVE BEEN INADEQUATE AND INEFFECTIVE.**

387. From the outset, Royal Philips has directly overseen and managed the Recall announced on June 14, 2021.

388. Royal Philips tasked a member of its Executive Committee, Roy Jakobs, with leading the company's repair and remediation program.<sup>352</sup> Mr. Jakobs is in charge of Philips' Connected Care businesses that include Philips RS.<sup>353</sup> Royal Philips claims that "[s]ince taking

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<sup>351</sup> See ResMed "Other Manufacturer Recall 2021" webpage, An update from ResMed's CEO (Dec. 6, 2021), <https://www.resmed.com/en-us/other-manufacturer-recall-2021/> (last accessed Oct. 4, 2022) (Exhibit "51" hereto).

<sup>352</sup> See Royal Philips Press Release, Philips announces CEO succession (Aug. 16, 2022) (Exhibit "41" hereto); see also video titled "Philips CEO Frans van Houten and Chief Business Leader Connected Care Roy Jakobs talk about the various aspects of the field safety notice," available at: <https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220628-philips-provides-update-on-philips-respironics-pe-pur-sound-abatement-foam-test-and-research-program.html> (last accessed Oct. 3, 2022). With respect to the Recall, Mr. Jakobs has said: "I have a dedicated team of over 1,000 colleagues fully focused on this [the repair and replacement program], supported by many more across the company." See also Royal Philips Press Release, Philips provides update on Philips Respironics' PE-PUR sound abatement foam test and research program (June 28, 2022), <https://www.usa.philips.com/healthcare/e/sleep/communications/src-update/news/philips-provides-update-on-philips-respironics-pe-pur-sound-abatement-foam-test-and-research-program> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "111").

<sup>353</sup> See Royal Philips First-Quarter Results 2022 (Apr. 25, 2022), available at: <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html> (last accessed Oct. 3, 2022) (Exhibit "40" hereto) ("Philips has a strong program management in place led by Roy Jakobs, Chief Business Leader of the Connected Care businesses and member of Philips' Executive Committee, to ensure the Respironics field action is executed with speed and accuracy."); see also Royal Philips Investor Call Transcript regarding "Test and research program Respironics PE-PUR sound abatement foam" (June 28, 2022), available at: <https://www.philips.com/c-dam/corporate/newscenter/global/standard/resources/healthcare/2022/podcast-healthier-future/Transcript - Philips Test and research program Respironics PE-PUR sound abatement foam.pdf> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "112").

on responsibility for the voluntary recall notification/field safety notice for specific Respironics devices on behalf of Philips, substantial progress has been made under his [Mr. Jakobs'] leadership in the execution of the comprehensive program aimed at delivering a resolution to affected patients as fast as possible in consultation with the relevant competent authorities.”<sup>354</sup>

389. In addition to Mr. Jakobs, Royal Philips' Technical Project Manager Jan Bennik “head[s] up the polyester-polyurethane sound abatement foam test and research program.”<sup>355</sup> He has spoken publicly on behalf of Philips about the recalled devices.

390. Further, the following additional Royal Philips employees are believed to have knowledge of the Recall of the devices<sup>356</sup>: a) Liz Iversen, Former Chief Quality and Regulatory

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<sup>354</sup> *Id.*

<sup>355</sup> Technical Project Manager Jan Bennik speaks about the test and research program, video available at: <https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html> (last accessed Oct. 3, 2022).

<sup>356</sup> *See* Letter dated September 15, 2022, from all Philips Defendants (attached hereto as Exhibit “113”), at 3-6 (section regarding agreed-upon initial custodians from which to pull responsive discovery).



Officer<sup>357</sup>; b) Jan Kimpen, Chief Medical Officer (Netherlands-based)<sup>358</sup>; and c) Carla Kriwet, Former Chief Business Leader Connected Care (Netherlands-based).<sup>359</sup>

391. Upon information and belief, Philips NA has also been involved with the Recalled Devices and the Recall.<sup>360</sup> For example:

- a. Tom Reimann, Head of Quality of Connected Care, likely “has knowledge regarding the manufacture, regulatory evaluation, and quality assurance review of certain devices and the recall of the devices.”<sup>361</sup>
- b. Thomas Catalano, Director of Product Marketing, is “Lead global product management team in \$1 bill sleep business unit.”<sup>362</sup> His prior role with Philips was as a Global product Manager, involved with “Development product/service pipeline for next generation of CPAP therapy to treat obstructive apnea.”<sup>363</sup>

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<sup>357</sup> Liz Iversen had “global executive responsibility and accountability” for Royal Philips. On LinkedIn, she described her role with Royal Philips as follows: “Global executive responsibility and accountability for Quality, Regulatory, Clinical, Medical and Compliance to ensure delivery of safe and effective products across the enterprise while executing regulatory and quality strategies in support of business growth.” LinkedIn Profile for Liz Iversen, Experience section, <https://www.linkedin.com/in/ediversen/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “114”).

<sup>358</sup> As Chief Medical Officer Jan Kimpen “worked collaboratively with business and functional leaders across the organization” including “provid[ing] clinical guidance for the development and market introduction of all new product...[and] advis[ing] Philips’ board and management in making decisions on market participation, product development, ...and product launches.” *See* LinkedIn profile for Jan Kimpen, Experience section (Exhibit “38” hereto).

<sup>359</sup> Ms. Kriwet’s LinkedIn Profile states she was the “CEO, Connected Care, Member of the Royal Philips Executive Committee” from 2017-2020. *See* LinkedIn Profile for Carla Kriwet, Experience section, <https://www.linkedin.com/in/dr-carla-kriwet/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “115”).

<sup>360</sup> *See* Letter dated September 15, 2022, from all Philips Defendants (Exhibit “113” hereto), at 3-6 (section regarding agreed-upon initial custodians from which to pull responsive discovery).

<sup>361</sup> Philips RS North America LLC’s Initial Disclosures, dated May 5, 2022 (attached hereto as Exhibit “116”).

<sup>362</sup> *See* LinkedIn Profile for Thomas Catalano, <https://www.linkedin.com/in/thomas-catalano-5a66552/> (last accessed Oct. 4, 2022) (attached hereto as Exhibit “117”).

<sup>363</sup> *Id.*

- c. Francis Kim, EVP Chief Quality & Regulatory Officer<sup>364</sup>;
- d. Erin Levering, Medical Safety Manager, was responsible for working “with the Post-Market Surveillance team to assess individual complaints for safety concerns and regulatory reporting requirements.”<sup>365</sup>;
- e. Vitor Rocha, Chief Market Leader – “CEO North America, EVP at Philips...responsible for driving growth, expanding market share and advancing Philips’ position...”<sup>366</sup>;
- f. Drilon Saliu, former Connected Care Head of Regulatory Affairs, October 2019 – September 3, 2021<sup>367</sup>; and
- g. Jessica Shen, Former Senior Vice President, Global Head of Medical Affairs, Clinical Affairs, HEOR & Regulatory Affairs. April 2015 – August 13, 2021.<sup>368</sup> – “Responsible for pre-market, regulatory approval for commercialization of products and solutions, including the development of key regulatory and clinical strategies to bring new technologies to market with the shortest possible cycle time; and the harmonization of regulatory/clinical processes across all Philips product lines; Work closely with global regulatory officials to further advance Philips’ relationship and reputation among these important groups; and continue to build out our core internal competencies and strengthen our regulatory, Medical & clinical team.”<sup>369</sup>

392. While the Recall began in the United States, it has been expanded worldwide.<sup>370</sup>

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<sup>364</sup> See LinkedIn Profile for Francis Kim, <https://www.linkedin.com/in/francis-k-2b32a111a> (last accessed Oct. 7, 2022) (attached hereto as Exhibit “118”); *see also* [REDACTED]

<sup>365</sup> See LinkedIn Profile for Erin Levering, [https://www.linkedin.com/in/erin-levering-bs-rn-certified-nurse-practitioner-034920178/?trk=public\\_post\\_comment-text](https://www.linkedin.com/in/erin-levering-bs-rn-certified-nurse-practitioner-034920178/?trk=public_post_comment-text) (last accessed Oct. 5, 2022) (attached hereto as Exhibit “120”).

<sup>366</sup> See LinkedIn Profile for Vitor Rocha, <https://www.linkedin.com/in/vitor-rocha-98582124/> (last accessed Oct. 4, 2022) (attached hereto as Exhibit “121”).

<sup>367</sup> [REDACTED]

<sup>368</sup> *Id.*

<sup>369</sup> See LinkedIn Profile for Jessica Shen, <https://www.linkedin.com/in/jessica-shen-md-ms-b386016/> (last accessed Oct. 4, 2022) (attached hereto as Exhibit “122”).

<sup>370</sup> See Philips website, Urgent Product Defect Correction in Australia (Recall for Product Correction in New Zealand) (Exhibit “9” hereto) (stating that a global recall notification was issued on June 14, 2021 and that recalls specific to Australia and New Zealand were issued on July 2, 2021). Other impacted countries include, but are not limited to, Canada, Israel, and Chile.

393. Since June 2021, Royal Philips has issued numerous press releases specifically providing information about the worldwide recall.<sup>371</sup>

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In addition to the litigation initiated against Philips in the United States, “Philips or its affiliates are also defendants in litigation in Australia, Canada, Chile, and Israel, as well as in smaller or individual actions in other countries.” Royal Philips First Quarter Results 2022 - Presentation at 37 (Apr. 25, 2022), available for download at <https://www.philips.com/a-w/about/news/archive/corpcorps/news/press/2022/philips-first-quarter-results-2022.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “123”). In a video produced by Royal Philips, Chief Business Leader of the Connected Care businesses Roy Jakobs said: “We have more than 5.5 million patients from over 100 countries who need a replacement.” See Philips video, available at: <https://www.philips.com/a-w/about/investor-relations/recall-sleep-and-respiratory/testing.html> (last accessed Oct. 3, 2022). For example, there are 350,000 affected Philips CPAP devices and 29,500 affected Philips ventilators in France. ANSM (France) – Public Hearing Comité Scientifique Temporaire (June 8, 2022) video, available at: <https://www.youtube.com/watch?v=ctvL0TcmWO8> (last accessed Oct. 3, 2022). In France, the Agence nationale de sécurité du médicament et des produits de santé (ANSM) had public hearings regarding the recall on June 8, 2022. Technical Project Manager Jan Bennik of Royal Philips was among the representatives of Philips who spoke at the hearings. *Id.* CEO van Houten has said that Philips is “[i]n close dialogue with regulators across the world.” Philips 2021 Annual Report at 5 (Exhibit “13” hereto). French prosecutors have opened a preliminary investigation into Philips’ recall. A spokesperson for the Paris public prosecutor’s office said the office had “taken up, as of June 20, 2022, complaints filed on the grounds of aggravated deception, involuntary attacks on physical integrity, endangerment of life of others and administration of harmful substances.” Charlotte Van Campenhout, French Prosecutors Probe Philips Respirator Recall, Reuters (Sept. 9, 2022), <https://www.reuters.com/business/healthcare-pharmaceuticals/french-prosecutors-probe-philips-respirator-recall-france-info-reports-2022-09-08/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “124”).

<sup>371</sup> See, e.g., Royal Philips Press Release, Philips issues recall notification\* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit “34” hereto); Philips Press Release, Philips starts repair and replacement program of first-generation DreamStation devices in the US in relation to earlier announced recall notification\* (Sept. 1, 2021) (Exhibit “10” hereto); Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification\* (Nov. 14, 2021) (Exhibit “35” hereto); Royal Philips Press Release, Philips provides update on the test and research program in connection with the CPAP, BiPAP and Mechanical Ventilator recall notification\* (Dec. 23, 2021), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2021/20211223-philips-provides-update-on-the-test-and-research-program-in-connection-with-the-cpap-bipap-and-mechanical-ventilator-recall-notification.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “125”); Royal Philips Press Release, Philips Respirionics provides update for the US on ongoing CPAP, BiPAP and Mechanical Ventilator field action (Mar. 10, 2022), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220311-philips->

394. Royal Philips also discusses the Recall and the alleged Defect in the products in other communications and press releases such as those about its quarterly results.<sup>372</sup>

395. For example, when the problems with the Recalled Devices were first announced to Philips' shareholders, Royal Philips included in its April 26, 2021 press release regarding First Quarter 2021 results, the following statement from CEO Frans van Houten: "Regretfully, we have identified a quality issue in a component that is used in certain sleep and respiratory care

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[respironics-provides-update-for-the-us-on-ongoing-cpap-bipap-and-mechanical-ventilator-field-action.html](#) (last accessed Oct. 3, 2022) (attached hereto as Exhibit "126"); Royal Philips Press Release, Philips Respironics provides update on filed MDRs in connection with the voluntary recall notification/field safety notice\* for specific CPAP, BiPAP and mechanical ventilator devices (May 24, 2022), <https://www.philips.com/a-w/about/news/archive/standard/news/press/2022/20220524-philips-respironics-provides-update-on-filed-mdrs-in-connection-with-the-voluntary-recall-notification-field-safety-notice.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "127"); Royal Philips Press Release, Philips provides update on Philips Respironics' PE-PUR sound abatement foam test and research program (June 28, 2022) (Exhibit "111" hereto).

<sup>372</sup> Philips announcement of 2021 First-Quarter Results (Apr. 26, 2021), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-first-quarter-results-2021.html> (last accessed Oct. 3, 2022) (Exhibit "106" hereto); Philips announcement of 2021 Second-Quarter Results (July 26, 2021), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-second-quarter-results-2021.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "128"); Philips announcement of 2021 Third-Quarter Results (Oct. 18, 2021), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2021/philips-third-quarter-results-2021.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "129"); Philips announcement of Fourth Quarter and Annual Results 2021 (Jan. 24, 2022), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-fourth-quarter-results-2021.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "130"); Philips announcement of First-Quarter Results 2022 (Apr. 25, 2022), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-first-quarter-results-2022.html> (last accessed Oct. 3, 2022) (Exhibit "40" hereto); Philips announcement of Second-Quarter Results 2022 (July 25, 2022), <https://www.philips.com/a-w/about/news/archive/corpcomms/news/press/2022/philips-second-quarter-results-2022.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit "131").

products, and are initiating all precautionary actions to address this issue, for which we have taken a EUR 250 million provision.”<sup>373</sup>

396. In the same press release, Royal Philips said: “Philips has determined from user reports and testing that there are possible risks to users related to the sound abatement foam used in certain of Philips’ sleep and respiratory care devices currently in use. The risks include that the foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone, and certain environmental conditions involving high humidity and temperature. The majority of the affected devices are in the first-generation DreamStation product family. Philips’ recently launched next-generation CPAP platform, DreamStation 2, is not affected. Philips is in the process of engaging with the relevant regulatory agencies regarding this matter and initiating appropriate actions to mitigate these possible risks.”<sup>374</sup>

397. In a June 14, 2021 press release, Royal Philips said: “Philips is initiating a voluntary recall notification to ensure patient safety in consultation with regulatory agencies.”<sup>375</sup> Royal Philips CEO van Houten said: “In consultation with the relevant regulatory agencies and in close collaboration with our customers and partners, we are working hard towards a resolution, which includes the deployment of the updated instructions for use and a comprehensive repair and replacement program for the affected devices.”<sup>376</sup>

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<sup>373</sup> Philips announces its 2021 First-Quarter Results (Apr. 26, 2021) (Exhibit “106” hereto).

<sup>374</sup> *Id.* (footnote omitted).

<sup>375</sup> Royal Philips Press Release, Philips issues recall notification\* to mitigate potential health risks related to the sound abatement foam component in certain sleep and respiratory care devices (June 14, 2021) (Exhibit “34” hereto) (asterisk and footnote omitted).

<sup>376</sup> *Id.*

398. This announcement from Royal Philips further stated that “Philips determined based on testing that there are possible risks to users related to this type of foam”; “Philips” decided to issue the recall notification; “Philips has received reports of possible patient impact due to foam degradation”; “Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction”; and “Philips’ recently launched next-generation CPAP platform” is not affected by the foam degradation issues.<sup>377</sup>

399. Mr. van Houten also stated in the Recall announcement on June 14, 2021: “We deeply regret any concern and inconvenience that patients using the affected devices will experience because of the proactive measures we are announcing today to ensure patient safety.”<sup>378</sup>

400. Later in 2021, Royal Philips emphasized its involvement in the Recall program in various publications. For example, a presentation on Royal Philips’ Fourth Quarter 2021 Results noted: “Regular review cadence with Respiroics field action Program Management and Executive Committee.”<sup>379</sup> The same presentation said: “Philips’ experts as well as certified labs and qualified third-party experts are working closely with the Respiroics team.”<sup>380</sup> The presentation also indicated an effort to “step-up company-wide program.”<sup>381</sup>

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<sup>377</sup> *Id.*

<sup>378</sup> *Id.*

<sup>379</sup> Philips Fourth Quarter and Full Year 2021 Results – Presentation at 39 (Jan. 24, 2022), available for download at <https://www.philips.com/a-w/about/news/archive/corpcorps/news/press/2022/philips-fourth-quarter-results-2021.html> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “132”).

<sup>380</sup> *Id.*

<sup>381</sup> *Id.* at 36.

401. The 2021 Philips Annual Report shows that in addition to Royal Philips' Management, Royal Philips' Supervisory Board and Royal Philips' Quality and Regulatory Committee were also involved in the Recall. For example, the Royal Philips Supervisory Board reported: "In view of the Philips Respironics voluntary recall notification related to the sound abatement foam in certain sleep and respiratory care products (announced on June 14, 2021), the Supervisory Board regularly discussed this issue and the progress made with respect to the repair and replacement program with Management."<sup>382</sup> Further, the Royal Philips Quality and Regulatory Committee reported that, at its meetings, it discussed "matters associated with [the recall], such as interactions with regulatory authorities globally, engagement with patients, physicians, customers and durable medical equipment providers, testing, health hazard evaluations, and the status of the repair and remediation plan."<sup>383</sup>

402. At the May 2022 shareholders meeting for Royal Philips, CEO van Houten said: "Our team is laser-focused on resolving the sleep recall."<sup>384</sup> He added, regarding the recall: "We have established a dedicated team of 1,000 colleagues working under the direct supervision of the Executive Committee."<sup>385</sup> He explained: "I can tell you that the Philips Board of Management became aware of the issue and its potential significance in the first quarter of 2021 and took adequate and immediate action. This resulted in the issuance of the field safety notice and start of the remediation actions in the first half of 2021."<sup>386</sup> Van Houten further stated that

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<sup>382</sup> Philips 2021 Annual Report (Exhibit "13" hereto), at 95.

<sup>383</sup> *Id.* at 115-16.

<sup>384</sup> Koninklijke Philips NV Annual Shareholders Meeting Transcript (May 10, 2022), Fair Disclosure Wire (attached hereto as Exhibit "133"), at 2.

<sup>385</sup> *Id.*

<sup>386</sup> *Id.*



[Royal Philips] took a lot of actions. We have, for example, onboarded new top management in the Sleep & Respiratory Care business. We strengthened quality and regulatory affairs leadership for the group for Connected Care, and for the Sleep & Respiratory care business. And we've also added resources to strengthen specific capabilities, all as the consequence of finding out about this issue.<sup>387</sup>

403. Royal Philips' CEO van Houten made frequent statements about the Recall. For example, in the 2021 Royal Philips Annual Report, Mr. van Houten said: "We identified – through our post-market surveillance processes – that **the sound abatement foam used since 2008 in certain of our sleep and respiratory care products may degrade under certain circumstances**. Subsequently, we issued a voluntary recall notification for affected devices to address potential health risks."<sup>388</sup> In July 2021, he said: "We have mobilized the necessary resources across the company to address the component quality issue in certain of our sleep and respiratory care products."<sup>389</sup> In a January 24, 2022 press release, he said, "we remain extremely focused on repairing and replacing the devices related to the Philips Respironics recall notification."<sup>390</sup> And in April 2022, he said, "[w]e have a strong program management in place overseeing every aspect of the remediation."<sup>391</sup>

404. On the same day that the FDA announced that reports of faulty Philips ventilators and sleep apnea machines had risen, Royal Philips announced that CEO van Houten would be stepping down.<sup>392</sup> CEO van Houten's departure announcement followed a May 2022 Royal

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<sup>387</sup> *Id.* at 8.

<sup>388</sup> Philips 2021 Annual Report (Exhibit "13" hereto), at 5 (emphasis added).

<sup>389</sup> Philips Second-Quarter Results 2021 (July 26, 2021) (Exhibit "128" hereto).

<sup>390</sup> Philips Fourth Quarter and Annual Results 2021 (Jan. 24, 2022) (Exhibit "130" hereto).

<sup>391</sup> Philips First Quarter Results 2022 (Apr. 25, 2022) (Exhibit "40" hereto).

<sup>392</sup> Toby Sterling and Bart H. Meijer, FDA says faulty Philips device reports accelerating as CEO departs, Reuters, Aug. 17, 2022, <https://www.reuters.com/business/healthcare->



Philips shareholders meeting where 80% of shareholders voted against giving Mr. van Houten a bonus. Shareholders were “unhappy about delivery problems and issues with the company’s widely used sleep apnea machines.”<sup>393</sup>

405. Royal Philips’ public statements demonstrate that it has been involved with U.S. regulatory authorities since the announcement of the Recall. In press releases and other statements, Royal Philips has discussed working with the FDA. For example, in a September 1, 2021 press release, Royal Philips said: “Philips received authorization from the US Food and Drug Administration (FDA) for the rework of the affected first-generation DreamStation devices, which consists of replacement of the PE-PUR sound abatement foam with a new material. Philips anticipates rework to commence in the course of September 2021. In addition to the rework, the company has already started replacing certain affected first-generation DreamStation CPAP devices in the US with DreamStation 2 CPAP devices. Philips remains in dialogue with the FDA with respect to other aspects of the recall notification and mitigation plan in the US.”<sup>394</sup>

406. Royal Philips issued the following statement in a November 14, 2021 press release: “‘In connection with the voluntary recall notification in June of this year, the FDA has recently conducted an inspection of a Philips Respironics manufacturing facility in the US,’ said Frans van Houten, CEO of Royal Philips. ‘We will work closely with the FDA to clarify and

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[pharmaceuticals/fda-says-faulty-philips-device-reports-accelerating-ceo-departs-2022-08-17/](https://www.pharmaceuticals/fda-says-faulty-philips-device-reports-accelerating-ceo-departs-2022-08-17/) (last accessed Oct. 3, 2022) (attached hereto as Exhibit “134”).

<sup>393</sup> Roy Jakobs to take over the helm at Philips as Frans van Houten steps down, DutchNews.nl (Aug. 16, 2022), <https://www.dutchnews.nl/news/2022/08/roy-jakobs-to-take-over-the-helm-at-philips-as-frans-van-houten-steps-down/> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “135”).

<sup>394</sup> Philips Press Release, Philips starts repair and/or replacement program of first-generation DreamStation devices in the US and other markets (Sept. 1, 2021) (Exhibit “10” hereto) (footnote omitted).

follow up on the inspectional findings and its recent requests related to comprehensive testing.”<sup>395</sup>

407. Royal Philips has also stated that it is involved in discussions with the Department of Justice relating to a Proposed Consent Decree. In its press release on Second Quarter 2022 results, Royal Philips said, “the US Department of Justice, acting on behalf of the FDA, recently began discussions with Philips regarding the terms of a proposed consent decree to resolve the identified issues [in inspection of U.S. facilities].”<sup>396</sup>

408. Unfortunately, Philips’ “recall” was a recall in name only. It did not effectively provide patients with notice of the risks of the Recalled Devices, nor did it provide them with new Philips CPAP, BiPAP, or ventilator devices.

**1. Many Patients, Providers, And Others Were Not Notified About The Recall.**

409. On March 10, 2022, the FDA issued a Notification Order under § 518(a) of the FDCA.<sup>397</sup> The Notification Order stated that the “FDA has received a number of calls from patients and consumers who contacted FDA to report problems and/or concerns regarding the Recalled Products, but were unaware of the recall and had not been informed of the health risks presented by the Recalled Devices.”<sup>398</sup>

410. The FDA estimated that, after nine months of the Recall, only “approximately 50% of patients and consumers who have purchased or received the Recalled Products

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<sup>395</sup> Royal Philips Press Release, Philips provides update on earlier announced voluntary CPAP, BiPAP and Mechanical Ventilator recall notification\* (Nov. 14, 2021) (Exhibit “35” hereto).

<sup>396</sup> Philips Second-Quarter Results 2022 (July 25, 2022) (Exhibit “131” hereto).

<sup>397</sup> See 518(a) Notification Order, available at: <https://www.fda.gov/media/156811/download> (last accessed Oct. 3, 2022) (attached hereto as Exhibit “136”).

<sup>398</sup> *Id.* at 2.

(excluding ventilators) within the last five years (the service life of the devices) have registered with Philips to obtain a replacement device.”<sup>399</sup> But it was “unclear whether the remaining patients and consumers have not registered because they are unaware of the need to register, or because they do not want or need a replacement device from Philips.”<sup>400</sup>

411. The FDA surveyed 182 consignees to determine whether they had been notified of the Recall and found 28 “who had reported to FDA that they were not aware of the recall.”<sup>401</sup> The FDA reported its results to Philips on September 8, 2021, and October 29, 2021, but Philips did not promptly respond. Almost a month later, on November 22, 2021, Philips stated that it had notified 23 of the 28 consignees of the Recall, but Philips did not “indicate whether the consignees identified by FDA had been sent notification before, or only after, they had been identified by FDA as being unaware of the recall.”<sup>402</sup> Moreover, Philips’ evidence of notification consisted of delivery confirmation receipts, reflecting that written correspondence was delivered to the consignees. As the FDA explained, “[t]ypically, firms demonstrate the effectiveness of its recall communications through evidence more meaningful than a delivery confirmation receipt, such as a returned response form or a documented telephone conversation.”<sup>403</sup>

412. Throughout the Recall, the FDA “on multiple occasions has informed Philips that FDA was concerned that Philips’ efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient,” and has expressed concern that “it is

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<sup>399</sup> *Id.*

<sup>400</sup> *Id.*

<sup>401</sup> *Id.*

<sup>402</sup> *Id.*

<sup>403</sup> *Id.* at 3.

likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.”<sup>404</sup>

413. Noting “Philips’ failure to timely provide effective notice to health professionals who prescribe or use the Recalled Products and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products,” the FDA issued an order under Section 518(a) of the FDCA ordering Philips to give adequate notice.<sup>405</sup> Specifically, the FDA ordered Philips to “notify all health professionals who prescribe or use the Recalled Products, and other persons (including consignees, distributors, retailers, and device users) who should be notified, of the recall and the health risks presented by the Recalled Products **within the next 45 days.**”<sup>406</sup>

**2. Philips’ Repair and Replacement Program Has Been Extremely Slow, Inadequate, and Ineffective.**

414. Those patients who registered their Recalled Devices with Philips for the Recall did not immediately receive replacement devices and were not told when a replacement device would be provided.

415. As Philips’ June 14, 2021 announcement explained:

**Repair and replacement program**

Philips is providing the relevant regulatory agencies with required information related to the launch and implementation of the projected correction. The company will replace the current sound abatement foam with a new material and has already begun the preparations, which include obtaining the relevant regulatory clearances. Philips aims to address all affected devices in scope of this correction as expeditiously as possible.

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<sup>404</sup> *Id.*

<sup>405</sup> *Id.* at 4.

<sup>406</sup> *Id.* (emphasis in original).

As part of the program, the first-generation DreamStation product families will be modified with a different sound abatement foam and shipped upon receipt of the required regulatory clearances. Philips' recently launched next-generation CPAP platform, DreamStation 2, is not affected by the issue. To support the program, Philips is increasing the production of its DreamStation 2 CPAP devices, that are available in the US and selected countries in Europe.<sup>407</sup>

416. In reality, patients may register their DreamStation Recalled Device with Philips for the Recall, but Philips has not immediately replaced the defective PE-PUR foam in the DreamStation Recalled Devices. Rather, patients have had to wait, sometimes for many months, for Philips to repair or replace their devices, and many patients are still waiting for a replacement device.

417. As of the date of this Complaint—over a year after the Recall was announced—Philips continues to repair or replace defective DreamStation 1 Recalled Devices. In other words, the Recall remains ongoing.

418. The replacement program for the Trilogy devices has been even slower. Philips has only just begun the rework of affected Trilogy 100/200 devices and Philips projects that the process will take approximately 12-14 months to complete.<sup>408</sup>

419. There is no repair or replacement program for any of the other Recalled Devices recalled by Philips.

420. Due to the design of the Recalled Devices, it is prohibitively difficult for patients to remove or replace the PE-PUR foam themselves. Also, the FDA warns:

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<sup>407</sup> See Food and Drug Administration, Philips Issues a Recall Notification\*, <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/philips-issues-recall-notification-mitigate-potential-health-risks-related-sound-abatement-foam> (last accessed Oct. 3, 2022).

<sup>408</sup> See Philips "Ventilation News and Updates" webpage, Trilogy Remediation Update for Business Customers (June 1, 2022) (Exhibit "11" hereto).

Do **not** try to remove the foam from your device. Trying to or successfully removing the foam may damage the device or change how the device works. It may also lead to more foam or chemicals entering the air tubing of the device.<sup>409</sup>

421. As a result, the Recall leaves patients without safe, free options. Instead, patients may simply be or were forced to buy Philips' next-generation product or a competitor's product—at full price, and indeed, thousands of patients, have already done so.

422. Thus, Philips intends to, and is, profiting from its “recall” by selling more of its next generation product, the DreamStation 2, whose launch appears intentionally timed to coincide with the “recall.”

423. The FDA also believes that the Recall is not proceeding quickly enough. It recently stated:

Based on the status of Philips' recall as of the date of this letter [May 2, 2022], CDRH believes that, if an order were to be issued to Philips under section 518(b), the plan submitted by Philips in response to that order should provide for significant improvements to Philips' ongoing repair and replacement activities to speed the pace of remediation and address other deficiencies identified by CDRH and communicated to Philips, to the extent such improvements are achievable by Philips.<sup>410</sup>

\* \* \*

424. As stated above, each Philips Defendant acted as part of one joint enterprise in connection with the design, development, testing, marketing, promotion, and sale of the defective and unreasonably dangerous Recalled Devices. Each Philips Defendant is also independently, directly responsible for the design, development, testing, marketing, promotion and sale of the defective and unreasonably dangerous Recalled Devices.

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<sup>409</sup> <https://www.fda.gov/medical-devices/safety-communications/faqs-philips-respironics-ventilator-bipap-machine-and-cpap-machine-recalls> (emphasis in original) (last accessed Oct. 3, 2022).

<sup>410</sup> 518(b) Notice (Exhibit “72” hereto), at 13.

425. Royal Philips has directly been involved with and independently contributed to, for example, the quality, regulatory, and medical compliance functions for Philips; the Recall both globally and in the United States (which it effectively controlled, managed and coordinated); a research program into the hazards posed by the PE-PUR foam; and through its Chief Medical Officer provides guidance for the development and market introduction of all new product development and launches. Royal Philips made the decision to purchase Philips RS (then Respironics) for \$5.6 billion, made the decision to pursue expansion of the CPAP, BiPAP, and ventilator product lines; uses and adheres to a worldwide mandatory training program, General Business Principles, and the Philips Business System to govern the activities of the other Philips Defendants; owns the intellectual property rights that cover the Recalled Devices and tightly controls and protects all of its intellectual property, including that of its CPAP, BiPAP, and ventilator devices, in its own name and in conjunction with Philips RS; and owns and is listed as the copyright holder for the User Manuals for the Recalled Devices. Until the Recall was announced in June 2021, Royal Philips failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices despite its obligations pursuant to the federal securities laws. And through Philips USA, Royal Philips has controlled and managed Philips RS and Philips NA while distributing profits accrued from the Recalled Devices to shareholders of Royal Philips' stock.

426. Philips NA has also been directly involved with and independently contributed to, for example, the design, development, and sale of the Recalled Devices through employees with responsibility for quality and regulatory functions, including pre- and post-market regulatory compliance, and by participating in multiple HHEs relating to customer complaints of foam degradation. Philips NA also had a leading role in the marketing and new product development

as it relates to the Recalled Devices. What's more, [REDACTED]

[REDACTED] Until the Recall was announced in June 2021, Philips NA failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices.

427. Philips RS likewise designed, manufactured, promoted, and sold the Recalled Devices. Philips RS further received and managed complaints relating to the Recalled Devices; tested and failed to test the biocompatibility of PE-PUR foam as an element of medical devices; and ultimately implemented the Recall. Philips RS also jointly coordinated with Royal Philips to protect all of Royal Philips' intellectual property, including that related to its CPAP, BiPAP, and ventilator devices. Until the Recall was announced in June 2021, Philips RS failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices.

## V. CLASS ALLEGATIONS

428. Plaintiffs bring this action individually and as a class action, pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3). Specifically, the Class consists of the following:

**Nationwide Class:** All persons or entities (including consumers, institutions, insurers, self-funded employers, and third-party payers) in the United States (including its Territories and the District of Columbia) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

Excluded from the Class are: (a) Defendants and their employees, officers, and directors; and (b) the Judge(s) assigned to this case.

429. Alternatively, and in addition, Plaintiffs seek certification on behalf of subclasses defined as more fully set forth below and collectively referred to as the "State Subclasses."



430. Plaintiffs Goodenough, Brengle, Byrge, De Journette, Lake Martin Hospital, and Elmore Hospital seek certification on behalf of a subclass defined as follows (“Alabama Subclass”):

**Alabama Subclass:** All persons or entities in Alabama (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

431. Plaintiffs ASEA Health Trust and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Alaska Subclass”):

**Alaska Subclass:** All persons or entities in Alaska (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

432. Plaintiffs Gilliard-Gunter, Groudan, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Arizona Subclass”):

**Arizona Subclass:** All persons or entities in Arizona (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

433. Plaintiff Autry seeks certification on behalf of a subclass defined as follows (“Arkansas Subclass”):

**Arkansas Subclass:** All persons or entities in Arkansas (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

434. Plaintiffs Bailey, Bastasch, Campbell, Krantz, Luenebrink, Mest, Mitrovich, Nielson, Ruiz, Waybright, and MSP seek certification on behalf of a subclass defined as follows (“California Subclass”):

**California Subclass:** All persons or entities in California (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in

whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

435. Plaintiffs Archuleta and McDaniel seek certification on behalf of a subclass defined as follows (“Colorado Subclass”):

**Colorado Subclass:** All persons or entities in Colorado (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

436. Plaintiffs Gottlieb, Rohan, Toscano, and MSP seek certification on behalf of a subclass defined as follows (“Connecticut Subclass”):

**Connecticut Subclass:** All persons or entities in Connecticut (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

437. Plaintiffs George and Gibbons seek certification on behalf of a subclass defined as follows (“Delaware Subclass”):

**Delaware Subclass:** All persons or entities in Delaware (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

438. Plaintiffs Boyd, Dzierzanowski, Fields, Morris, Paraday, Smith, Ward, Ohio Carpenters, and MSP seek certification on behalf of a subclass defined as follows (“Florida Subclass”):

**Florida Subclass:** All persons or entities in Florida (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

439. Plaintiffs Childre, Davis, Fultz, Lewis, Luke, Mercure, and Sizemore seek certification on behalf of a subclass defined as follows (“Georgia Subclass”):

**Georgia Subclass:** All persons or entities in Georgia (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

440. Plaintiff Brown seeks certification on behalf of a subclass defined as follows (“Hawaii Subclass”):

**Hawaii Subclass:** All persons or entities in Hawaii (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

441. Plaintiff Savoure seeks certification on behalf of a subclass defined as follows (“Idaho Subclass”):

**Idaho Subclass:** All persons or entities in Idaho (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

442. Plaintiffs Baran, Brooks, Rootberg, and MSP seek certification on behalf of a subclass defined as follows (“Illinois Subclass”):

**Illinois Subclass:** All persons or entities in Illinois (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

443. Plaintiffs Diane Anderson, Clark, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Indiana Subclass”):

**Indiana Subclass:** All persons or entities in Indiana (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

444. Plaintiffs Abarr, Diamond, and Wilson seek certification on behalf of a subclass defined as follows (“Iowa Subclass”):

**Iowa Subclass:** All persons or entities in Iowa (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

445. Plaintiff Cathers seeks certification on behalf of a subclass defined as follows (“Kansas Subclass”):

**Kansas Subclass:** All persons or entities in Kansas (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

446. Plaintiffs Ratliff and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Kentucky Subclass”):

**Kentucky Subclass:** All persons or entities in Kentucky (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

447. Plaintiffs Baudoin, Couch, Gilliard-Gunter, Susan Martin, and Romas seek certification on behalf of a subclass defined as follows (“Louisiana Subclass”):

**Louisiana Subclass:** All persons or entities in Louisiana (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

448. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz seek certification on behalf of a subclass defined as follows (“Maine Subclass”):

**Maine Subclass:** All persons or entities in Maine (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

449. Plaintiff Dzierzanowski seeks certification on behalf of a subclass defined as follows (“Maryland Subclass”):

**Maryland Subclass:** All persons or entities in Maryland (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

450. Plaintiffs Bellotti, Conley, Whaley, and MSP seek certification on behalf of a subclass defined as follows (“Massachusetts Subclass”):

**Massachusetts Subclass:** All persons or entities in Massachusetts (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

451. Plaintiffs Wilks, Ohio Carpenters, and MSP seek certification on behalf of a subclass defined as follows (“Michigan Subclass”):

**Michigan Subclass:** All persons or entities in Michigan (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

452. Plaintiffs Boudreau and Mold seek certification on behalf of a subclass defined as follows (“Minnesota Subclass”):

**Minnesota Subclass:** All persons or entities in Minnesota (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

453. Plaintiffs Godeaux, Rankin and Tucker seek certification on behalf of a subclass defined as follows (“Mississippi Subclass”):

**Mississippi Subclass:** All persons or entities in Mississippi (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

454. Plaintiffs Brengle and Young seek certification on behalf of a subclass defined as follows (“Missouri Subclass”):

**Missouri Subclass:** All persons or entities in Missouri (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

455. Plaintiff David seeks certification on behalf of a subclass defined as follows (“Montana Subclass”):

**Montana Subclass:** All persons or entities in Montana (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

456. Plaintiff Lemus seeks certification on behalf of a subclass defined as follows (“Nevada Subclass”):

**Nevada Subclass:** All persons or entities in Nevada (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

457. Plaintiffs Lizotte, Malone, and Vlahos seek certification on behalf of a subclass defined as follows (“New Hampshire Subclass”):

**New Hampshire Subclass:** All persons or entities in New Hampshire (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

458. Plaintiffs Dennis, Gold, Ryan, Taylor, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“New Jersey Subclass”):

**New Jersey Subclass:** All persons or entities in New Jersey (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

459. Plaintiff Rodgers seeks certification on behalf of a subclass defined as follows (“New Mexico Subclass”):

**New Mexico Subclass:** All persons or entities in New Mexico (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

460. Plaintiffs Bossey, Ginsberg, Gold, and MSP seek certification on behalf of a subclass defined as follows (“New York Subclass”):

**New York Subclass:** All persons or entities in New York (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

461. Plaintiffs Bartalo and Margoles seek certification on behalf of a subclass defined as follows (“North Carolina Subclass”):

**North Carolina Subclass:** All persons or entities in North Carolina (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

462. Plaintiffs Flick, Fultz, Giordano, Hock, Stefanini, Ward, Ohio Carpenters, and MSP seek certification on behalf of a subclass defined as follows (“Ohio Subclass”):

**Ohio Subclass:** All persons or entities in Ohio (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

463. Plaintiffs Mcelyea and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Oklahoma Subclass”):

**Oklahoma Subclass:** All persons or entities in Oklahoma (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

464. Plaintiffs Julie Barrett, Peter Barrett, and Nielson seek certification on behalf of a subclass defined as follows (“Oregon Subclass”):

**Oregon Subclass:** All persons or entities in Oregon (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

465. Plaintiffs Masington, Sweeney, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Pennsylvania Subclass”):

**Pennsylvania Subclass:** All persons or entities in Pennsylvania (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

466. Plaintiffs Bonano and MSP seek certification on behalf of a subclass defined as follows (“Puerto Rico Subclass”):

**Puerto Rico Subclass:** All persons or entities in Puerto Rico (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

467. Plaintiffs Lamontagne, Weiner, and MSP seek certification on behalf of a subclass defined as follows (“Rhode Island Subclass”):

**Rhode Island Subclass:** All persons or entities in Rhode Island (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

468. Plaintiffs William Anderson and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“South Carolina Subclass”):

**South Carolina Subclass:** All persons or entities in South Carolina (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

469. Plaintiffs Cote, Craig, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Tennessee Subclass”):



**Tennessee Subclass:** All persons or entities in Tennessee (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

470. Plaintiffs Claunch, Cline, Deleon, Lowney, Malone, Panzera, Rendon, Tobin, Turner, Ohio Carpenters, and MSP seek certification on behalf of a subclass defined as follows (“Texas Subclass”):

**Texas Subclass:** All persons or entities in Texas (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

471. Plaintiff Ohio Carpenters seeks certification on behalf of a subclass defined as follows (“Utah Subclass”):

**Utah Subclass:** All persons or entities in Utah (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

472. Plaintiff David Martin seeks certification on behalf of a subclass defined as follows (“Vermont Subclass”):

**Vermont Subclass:** All persons or entities in Vermont (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

473. Plaintiffs Heilman, Hudson, Rodgers, Rose, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“Virginia Subclass”):

**Virginia Subclass:** All persons or entities in Virginia (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

474. Plaintiffs Lopez and Peebles seek certification on behalf of a subclass defined as follows (“Washington Subclass”):

**Washington Subclass:** All persons or entities in Washington (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

475. Plaintiffs Bays, Hamlin, Rucker, and Ohio Carpenters seek certification on behalf of a subclass defined as follows (“West Virginia Subclass”):

**West Virginia Subclass:** All persons or entities in West Virginia (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

476. Plaintiffs Matters and MSP seek certification on behalf of a subclass defined as follows (“Wisconsin Subclass”):

**Wisconsin Subclass:** All persons or entities in Wisconsin (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it.

477. Plaintiffs also seek to represent the claims of: All persons or entities in the District of Columbia (“D.C. Subclass”), Nebraska (“Nebraska Subclass”), North Dakota (“North Dakota Subclass”), South Dakota (“South Dakota Subclass”), and Wyoming (“Wyoming Subclass”) (including consumers, institutions, insurers, self-funded employers, and third-party payers) who, in whole or part, paid for or reimbursed payment for a Recalled Device or a device to replace a Recalled Device, but did not resell it. The claims of persons and entities in the District of Columbia, Nebraska, North Dakota, South Dakota, and Wyoming share common questions of fact and law that predominate over any individualized issues.

478. Excluded from the Subclasses are: (a) Defendants and their employees, officers, and directors; and (b) the Judge(s) assigned to this case.

479. Together, the Nationwide Class and the Subclasses shall collectively be referred to herein as the “Class.”

480. Plaintiffs reserve the right to adjust, modify, or narrow the Class prior to class certification.

481. The rights of each member of the Class were violated in a similar fashion based upon Defendants’ uniform actions.

482. This action has been brought and may be properly maintained as a class action for the following reasons:

a. Numerosity: Members of the Class are so numerous that their individual joinder is impracticable. The proposed Class contains at least millions of individuals or entities who paid for or reimbursed payment for a Recalled Device. The Class is therefore sufficiently numerous to make joinder impracticable, if not impossible. The precise number of Class members is unknown to Plaintiffs at this time, but the Class members are readily ascertainable and can be identified by Philips’ records and records of third parties, such as durable medical equipment providers.

b. Existence and Predominance of Common Questions of Fact and Law: Common questions of law and fact exist as to all members of the Class. These questions predominate over any questions affecting only individual Class members. These common legal and factual questions include, without limitation:

- i. Whether Defendants violated RICO by selling the Recalled Devices;
- ii. Whether Defendants were unjustly enriched by the sale of Recalled Devices;
- iii. Whether Defendants failed to warn consumers regarding the risks of the Recalled Devices;

- iv. Whether Philips violated express or implied warranties in selling the Recalled Devices;
- v. Whether Philips' practices constitute unfair or deceptive acts or practices under state consumer protection statutes;
- vi. The appropriate nature of class-wide equitable relief;
- vii. The appropriate measurement of restitution and/or measure of damages to Plaintiffs, and members of the Class;
- viii. The appropriate measure of statutory damages; and
- ix. Whether Plaintiffs are entitled to punitive damages.

These and other questions of law or fact which are common to the members of the Class predominate over any questions affecting only individual members of the Class.

c. Typicality: Plaintiffs' claims are typical of the claims of all members of the Class.

d. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class that they seek to represent; they have retained counsel competent and highly experienced in complex class action litigation and they intend to prosecute this action vigorously. The interests of the Class will be fairly and adequately protected by Plaintiffs and their counsel.

e. Superiority: A class action is superior to other available means of fair and efficient adjudication of the claims of Plaintiffs and the Class. The injury suffered by each Class member is relatively small in comparison to the burden and expense of individual prosecution of the complex and extensive litigation necessitated by Defendants' conduct. It would be virtually impossible for members of the Class to individually and effectively redress the wrongs done to them. Even if the members of the Class could afford such individual litigation, the court system could not. Individualized litigation presents a potential for inconsistent or contradictory

judgments. Individualized litigation also increases the delay and expense to all parties, and to the court system, presented by the complex legal and factual issues of the case. By contrast, the class action device presents far fewer management difficulties, and provides the benefits of single adjudication, an economy of scale, and comprehensive supervision by a single court.

## **VI. EQUITABLE TOLLING OF STATUTES OF LIMITATIONS**

483. The running of any statute of limitations has been equitably tolled by Defendants' fraudulent concealment and/or omissions of critical safety information. Through its affirmative misrepresentations and omissions, Philips actively concealed from Plaintiffs and physicians the true risks associated with the Recalled Devices.

484. As a result of Defendants' actions, Plaintiffs were unaware, and could not have reasonably known or learned through reasonable diligence, that the Recalled Devices were defective and exposed users to the risks and harms set forth here and that those risks and harms were the direct and proximate result of Defendants' acts and omissions.

## **VII. CAUSES OF ACTION**

### **COUNT 1 – VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1962(c), AGAINST PHILIPS AND POLYTECH** **On behalf of the Nationwide Class and all Subclasses<sup>411</sup>**

485. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

486. This claim is brought by Plaintiffs against the Philips Defendants and the PolyTech Defendants (within this claim, the "RICO Defendant(s)") for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq.*

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<sup>411</sup> Plaintiffs will submit a RICO case statement pursuant to Local R. Civ. P. 7.1.B within 14 days.

487. Pursuant to 18 U.S.C. § 1962(c): “It shall be unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity . . . .”

488. At all relevant times, each RICO Defendant is and has been a “person” under 18 U.S.C. § 1961(3) because each was capable of holding “a legal or beneficial interest in property.”

489. Philips and PolyTech each violated 18 U.S.C. § 1962(c) and injured the business or property of the Plaintiffs and the Nationwide Class. Plaintiffs are each a “person,” as defined in 18 U.S.C. § 1961(3). Further, Plaintiffs have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business and/or property “by reason of” the RICO Act violations described herein.

**a. The Philips-PolyTech Enterprise Was An Association-In-Fact Enterprise With A Common Purpose To Conceal The Health And Safety Risks Of The Recalled Devices.**

490. Philips and PolyTech conducted or participated in the affairs of an “association-in-fact enterprise”—*i.e.*, the Philips-PolyTech Enterprise—through a pattern of racketeering activity (stemming from the predicate racketeering acts of mail and wire fraud) in violation of 18 U.S.C. § 1962(c). The Philips-PolyTech Enterprise engaged in this pattern of illegal activities in furtherance of its common purpose to unlawfully defraud and mislead the FDA, prescribers, third-party payors, hospitals, and consumers about the safety of the Recalled Devices. In so doing, each of the RICO Defendants knowingly conducted and participated in mail and wire fraud in violation of 18 U.S.C. ¶¶ 1962(c) and (d).

491. The Philips-PolyTech Enterprise included Philips and PolyTech, as well as other nonparty individuals and corporations, including Paramount Die. Discovery will likely reveal additional members of the Philips-PolyTech Enterprise that are not currently known to Plaintiffs.

492. Each RICO Defendant participated in the Philips-PolyTech Enterprise and played a distinct role in furthering the enterprise's common purpose of knowingly concealing information about the safety of the Recalled Devices to increase profits.

493. Specifically, the RICO Defendants worked together to coordinate the enterprise's goals, conceal the existence of the enterprise, and conceal their individual roles. Further, each of the RICO Defendants were linked through their business relationships and continuing coordination of activities. This business relationship facilitated the formation of a common purpose among the RICO Defendants, who each agreed to participate in the conduct of the Philips-PolyTech Enterprise. Specifically, each RICO Defendant played a critical role in producing the Recalled Devices, concealing the Recalled Devices' defective condition, and selling the Recalled Devices.

494. At all relevant times, the Philips-PolyTech Enterprise: (i) had an existence that was separate and distinct from the individual RICO Defendants and their members; (ii) was separate and distinct from the pattern of racketeering in which the individual RICO Defendants engaged; (iii) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of the RICO Defendants; (iv) was characterized by relationships between and among each RICO Defendant; and (v) had sufficient longevity for the enterprise to pursue its common purpose and function as a unit.

495. The RICO Defendants participated in the conduct of the Philips-PolyTech Enterprise through a pattern of racketeering activity that employed the use of mail and wire

facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud). This was done to increase profits by hiding and misrepresenting the dangers associated with the Recalled Devices.

496. The Philips-PolyTech Enterprise engaged in and affected interstate commerce because it manufactured, marketed, sold, or provided the Recalled Devices to millions of individuals and entities throughout the United States.

**b. The Philips-PolyTech Enterprise Had A Common Purpose.**

497. The Philips-PolyTech Enterprise came together for the common purpose of perpetuating a fraudulent scheme to conceal the true health and safety risks associated with the Recalled Devices and PE-PUR foam from patients, prescribers, third-party payors, hospitals, and the FDA. This concealment was intended to allow the Enterprise participants to profit, continue to profit, and retain profits from the sale of Recalled Devices.

498. By knowingly concealing and minimizing the Defect, the RICO Defendants could represent the Recalled Devices as being safe and effective while omitting information to the contrary. These false representations, half-truths, and related omissions resulted in significant sales and revenue generated from the sale of defective Recalled Devices. Concealing and minimizing the Defect also allowed the RICO Defendants to avoid or limit the substantial costs and reputational harm associated with a recall, repair or replacement of the Recalled Devices.

499. Each of the RICO Defendants profited, directly or indirectly, from the scheme. These profits were substantially greater than they would have been if the Defect and true risks of the Recalled Devices had been disclosed.

- a. Philips profited directly from the sales of the Recalled Devices, which resulted from the Enterprise's deception of consumers, prescribers, third-party payors, hospitals, and the FDA.



- b. Likewise, PolyTech profited from the sale of the Recalled Devices that contained the PE-PUR foam cut and/or sold by PolyTech.
- c. Paramount Die likewise profited from the sale of the Recalled Devices that contained the PE-PUR foam modified by Paramount Die for use in the Recalled Devices.

500. Because the RICO Defendants' ability to profit from this scheme depended on the prescription and sale of the Recalled Devices, the Philips-PolyTech Enterprise needed to ensure complete allegiance to a false premise: that the Recalled Devices were safe and effective. For this scheme to work, it was essential for the Philips-PolyTech Enterprise to conceal the Defect from the FDA, because the agency could otherwise investigate, recall the devices, and notify the public of the Defect. The expense of a recall and the resulting inability to sell the defective Recalled Devices would undermine the profitability of the scheme.

501. This common purpose served the interests of all the RICO Defendants.

**c. The Philips-PolyTech Enterprise Had An Ongoing Organization.**

502. The RICO Defendants, in concert with the other Enterprise participants, created and maintained systematic links toward this common purpose, *i.e.*, to manufacture, market, and sell the Recalled Devices while concealing their health and safety risks.

503. The Philips-PolyTech Enterprise continued for several years, beginning no later than 2015 and continuing to the present. During this time, the RICO Defendants remained stable, with Philips, PolyTech, and Paramount Die actively producing, marketing, and selling the defective Recalled Devices.

504. The RICO Defendants exerted control over the Enterprise and have coordinated and participated in the operation or management of Enterprise affairs. At the same time, the

RICO Defendants were and are separate entities existing outside the Enterprise. The RICO Defendants' independent existences are demonstrated by the following:

- a. During the relevant period, Philips contemporaneously designed, manufactured and sold many medical devices and products separate and apart from the Recalled Devices.
- b. During the relevant period, PolyTech contemporaneously sold and distributed many other noise abatement products aside from the PE-PUR foam used in the Recalled Devices.
- c. During the relevant period, Paramount Die contemporaneously provided cutting services for rubber, foam, plastic and other materials apart from the PE-PUR foam used in the Recalled Devices.

505. The RICO Defendants also occupied delineated roles that furthered the organization's goals. Each RICO Defendant performed important but separate roles within the Philips-PolyTech Enterprise organization.

506. Philips participated in the conduct of the Enterprise when it, among other things:

- a. Designed, marketed, manufactured, and sold the Recalled Devices;
- b. Coordinated with PolyTech and Paramount Die to select and order the PE-PUR foam to use for sound abatement in the Recalled Devices;
- c. Downplayed, ignored, and failed to investigate issues of foam degradation in its devices using PE-PUR foam for sound abatement, including failing to perform and document required risk analyses;
- d. Obscured and minimized the Defect in the Recalled Devices by misleadingly blaming other factors, such as the use of ozone cleaners,

when faced with recurring evidence of serious problems (*e.g.*, including consumer complaints of “black dust” and related issues);

- e. Communicated and coordinated regularly with PolyTech about known instances of foam degradation and consumer complaints for devices with PE-PUR foam, beginning no later than 2015;
- f. Failed to implement a preventative maintenance procedure for Trilogy ventilator devices with PE-PUR foam that was successfully instituted by another Philips entity;
- g. Concealed that the Recalled Devices were equipped with defective PE-PUR foam that could degrade and emit dangerous VOCs; and
- h. Collected revenue flowing from the sale of the Recalled Devices.

507. PolyTech participated in the conduct of the Enterprise when it, among other things:

- a. Obtained bulk PE-PUR foam from Burnett, and cut, shipped, and sold PE-PUR foam for installation in the Recalled Devices;
- b. Disregarded specific warnings from Burnett about PE-PUR foam, and continued to obtain and sell the defective PE-PUR foam for use in the Recalled Devices;
- c. Relayed communications from Philips to Burnett, including as to questions about the PE-PUR foam chemistry and the safety risks, field issues, and testing for the Recalled Devices;
- d. Concealed that the Recalled Devices were equipped with defective PE-PUR foam that could degrade and emit dangerous VOCs;

- e. Misrepresented the PE-PUR foam in the Recalled Devices to be effectively resistant to heat and humidity;
- f. Communicated with Philips about known instances of foam degradation and consumer complaints for devices with PE-PUR foam; and
- g. Collected revenue flowing from the sale of the Recalled Devices.

508. In addition, each of the RICO Defendants separately ensured that the FDA, prescribers, third-party payors, hospitals, and consumers did not discover the Defect in the Recalled Devices.

509. Without the RICO Defendants' willing participation in the conduct above, the Enterprise's scheme and common course of conduct would have been unsuccessful.

510. The participants' dedication of personnel to the Enterprise's scheme further evidences the ongoing structure of the Enterprise. For example,

- a. PolyTech dedicated its employees Bob Marsh and Bonnie Peterson to work with Philips relating to the PE-PUR foam in the Recalled Devices, and to coordinate their communications with Burnett on behalf of Philips. Ms. Peterson served as a regular point of contact for technical questions about the PE-PUR foam, while Mr. Marsh liaised with Philips' personnel on foam degradation issues and questions. Likewise, PolyTech dedicated its employee Michael Haupt to coordinate with Paramount Die.
- b. Philips, for its part, dedicated key personnel to the Recalled Devices' design, marketing or sale, and/or to contacting PolyTech. This included Vince Testa, who attended internal meetings on foam degradation issues

and who was then designated as a point of contact for PolyTech as a follow-up to those meetings.

- c. Establishing these regular points of contact further organized the Enterprise.

511. The RICO Defendants were aware of the other member's involvement with the Enterprise and aided its purposes by conducting illegal and fraudulent acts, *i.e.*, mail and wire fraud. Accordingly, each member of the Enterprise benefited from the involvement and existence of the others.

- d. **The RICO Defendants Committed At Least Two Predicate Acts Of Mail And Wire Fraud In Furtherance Of The Enterprise's Fraudulent Scheme.**

512. The RICO Defendants devised a scheme for the purpose of defrauding consumers, prescribers, third-party payors, hospitals, and the FDA by falsely concealing or minimizing the Defect in the Recalled Devices.

513. In addition, the RICO Defendants devised an illicit scheme for the purpose of obtaining money by fraudulent pretenses to maximize sales of the Recalled Devices. This scheme ultimately financially enriched the RICO Defendants.

514. In furtherance of the scheme, the RICO Defendants knowingly conducted or participated, directly or indirectly, in the Philips-PolyTech Enterprise through racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c). Specifically, the RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of, *at least* two predicate acts of racketeering activity within the past ten years, therefore constituting a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels and employees

of the Philips-PolyTech Enterprise, the U.S. Mail and interstate wire facilities. The RICO Defendants participated in the scheme to defraud by using mail, telephones and Internet to transmit mailings and wires in interstate or foreign commerce.

515. The RICO Defendants used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of the enterprise's objectives through misrepresentations, concealments, and material omissions.

516. The RICO Defendants caused such mailings and uses of the wire to be made either by directly making or approving certain fraudulent statements or by setting in motion a scheme to defraud that would reasonably lead to those mailings and wirings. These multiple acts of racketeering activity were related to each other, pose a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

517. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the Recalled Devices by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful

scheme to defraud and obtain money on false pretenses, misrepresentations, promises, and omissions.

518. The RICO Defendants' uses of the mails and wires include, but are not limited to, the transmission, delivery, or shipment of the following by the RICO Defendants or third parties that were foreseeably caused to be sent in furtherance and as a result of the RICO Defendants' illegal scheme to defraud:<sup>412</sup>

- a. Shipments by Philips of the Recalled Devices, known to be defective, to locations throughout the United States for distribution and sale. Plaintiffs do not have access to the confidential records that provide the precise dates and locations of these shipments, which occurred in each year beginning no later than 2015 and continuing through 2021. The Recalled Devices transported in interstate commerce were misbranded, in violation of 21 U.S.C. § 352.
- b. Shipments from PolyTech to Philips (including *via* Paramount Die) of the PE-PUR foam for installation in the Recalled Devices, knowing that Philips would use the foam in the defective Recalled Devices and distribute the Recalled Devices throughout the United States using interstate carriers. Plaintiffs do not have access to the confidential records that provide the precise dates and locations of these shipments, which

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<sup>412</sup> Many of the precise dates and examples of the uses of the U.S. Mail and interstate wire facilities to further their fraudulent scheme cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred.

occurred in each year beginning no later than 2015 and continuing through 2021.

- c. Shipments by Burnett of bulk PE-PUR foam sheets by private or commercial interstate carrier to PolyTech for use in the Recalled Devices. PolyTech caused Burnett to make these shipments when it ordered the bulk foam, knowing it would then transmit the foam for installation in the Recalled Devices. Plaintiffs do not have access to the confidential records that provide the precise dates and locations of these shipments, which occurred in each year beginning no later than 2015 and continuing through 2021. Documents provided to date from Burnett provide the particulars of at least one such shipment, which originated from Burnett in Baltimore, Maryland and was shipped to PolyTech in Newark, Delaware, on or about March 12, 2021.<sup>413</sup>
- d. Advertisements, brochures, labeling, and marketing from Philips that omitted the known health and safety risks of the Recalled Devices, distributed using mail, wire, radio, or television communications in interstate commerce. This includes transmission of statements from Philips that its “sleep therapy systems are designed with the needs of care practitioners and patients in mind” and the numerous other misrepresentations related to safety and efficacy cited above. *See* ¶¶ 213-14, *supra*. Each such mailed advertisement—including brochures or print

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<sup>413</sup> *See* Purchase Order dated 3/12/2021 and supporting documentation (Lawler Aff. Exh. B) (attached hereto as Exhibit “138”), at WTB 000015-50.



advertisements—violated the mail fraud statute (18 U.S.C. § 1341). Each such internet-based, radio, and television advertisement was a violation of the wire fraud statute (18 U.S.C. § 1343). Philips knew its advertisements about the Recalled Devices were misleading and omitted material information, but still disseminated the advertisements to ensure the continued prescription and sale of the Recalled Devices.

- e. Advertisements and marketing from PolyTech for the PE-PUR foam used in the Recalled Devices, including marketing that falsely misrepresented the foam to have “superior physical properties and offer excellent resistance to heat, moisture, and chemicals.” Each such mailed advertisement was a violation of the mail fraud statute (18 U.S.C. § 1341). Each such internet-based, radio, and television advertisement was a violation of the wire fraud statute (18 U.S.C. § 1343). PolyTech knew its advertisements were misleading and omitted material information, but still disseminated the advertisements to ensure the continued prescription and sale of the Recalled Devices.
- f. Documents necessary to facilitate the sale and transmission of bulk PE-PUR foam from Burnett for use in the Recalled Devices, including invoices, packing lists, labels, invoices, and test reports.<sup>414</sup> Each RICO Defendant knew that these documents would foreseeably result in the

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<sup>414</sup> See Lawler Aff. (Exhibit “94” hereto), at ¶ 20; *see also* Purchase Orders and supporting documentation (Lawler Aff. Exh. B) (Exhibit “138” hereto), at WTB 000015-50.

manufacture and sale of the Recalled Devices, thereby furthering the scheme to continue to make and sell them without disclosing the Defect.

- g. Documents necessary to facilitate the manufacture and sale of the Recalled Devices, including bills of lading, invoices, shipping records, reports and correspondence. Each of the RICO Defendants knew that these documents would foreseeably result in the manufacture and sale of the Recalled Devices, thereby furthering the scheme to continue to make and sell them without disclosing the Defect.
- h. Documents necessary to process and receive payment for the Recalled Devices by unsuspecting Plaintiffs and Class members, including invoices and receipts. Each of the RICO Defendants knew that these documents were the foreseeable result of the manufacture and sale of the Recalled Devices, thereby furthering their scheme to continue to make and sell them without disclosing the Defect.
- i. False or misleading communications, internally to Philips and PolyTech and externally with third parties including Burnett, that obscured the Defect and prevented regulators and the public from discovering the true risks of the Recalled Devices, and/or purposely misidentified the cause of issues in the Recalled Devices to external factors, such as ozone cleaners.
- j. While using mail and wire to defraud and obtain revenue under false pretenses, Philips and PolyTech failed to timely, accurately, and completely disclose the Defect and associated risks in the Recalled

Devices when Philips and PolyTech had a duty to disclose this information.<sup>415</sup>

519. The RICO Defendants (or their agents), in furtherance of their illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of the Recalled Devices and related documents and communications. Because the RICO Defendants disguised their participation in the Enterprise, and worked to keep the Enterprise's existence secret so as to give the false impression that the Recalled Devices were safe, many of the precise dates of the Enterprise's use of U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the RICO Defendants' records. Indeed, an essential part of the successful operation of the Philips-PolyTech Enterprise alleged herein depended upon secrecy. However, Plaintiffs describe occasions on which the RICO Defendants disseminated misrepresentations and false statements to consumers, prescribers, regulators, and Plaintiffs, and how those acts advanced the scheme. These disseminations include:

<u>From</u>	<u>To</u>	<u>Date</u>	<u>Description</u>
Philips	PolyTech	October 30, 2015	Email message from Philips to PolyTech sharing information and implying that a customer made Philips aware of PE-PUR foam degradation issues.
PolyTech	Burnett	October 30, 2015	Email message from PolyTech to Burnett transmitting information from Philips about PE-PUR foam degradation issues.

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<sup>415</sup> As explained below, Philips and PolyTech had multiple independent duties to disclose material information about the Recalled Devices, which they failed to fulfill.

Philips entity	Philips	November 25, 2015	Communications transmitting information about a preventative maintenance servicing procedure implemented on Trilogy devices by a Philips entity, which resulted in no documented further investigation, risk analysis, or design review. <sup>416</sup>
Bob Marsh, PolyTech	Lee Lawler, Burnett	August 5, 2016	Email message from Bob Marsh of PolyTech to Lee Lawler of Burnett, referring to questions from Philips, and admitting that PolyTech would inform Philips of risks of PE-PUR foam raised by Burnett in 2016.
Philips		April 1, 2016 to January 22, 2021	Documents and communications sharing results of at least fourteen instances, assessments, and/or test reports, where Philips was aware of issues and concerns related to potential foam degradation and/or Volatile Organic Compound (VOC) emissions, with various Sleep and Respiratory care devices.
Vincent Testa, Philips	Bonnie Peterson, PolyTech	April 20, 2018	Email reporting consumer complaints that PE-PUR foam in Trilogy devices was “disintegrating” and admitting it was a “potential safety concern.”
Bob Marsh, PolyTech	Lee Lawler, Burnett	April 23, 2018	Email correspondence regarding degradation of ester foam, and forwarding email

<sup>416</sup> See 483 Report (Exhibit “5” hereto), at 2.

			from Vince Testa of Philips regarding the same. <sup>417</sup>
Bob Marsh, PolyTech (with Bonnie Peterson and Mike Haupt, PolyTech)	Lee Lawler, Burnett	May 2, 2018 and May 4, 2018	Email correspondence confirming Philips' test results for ether vs. ester foam confirming that ether was the "better performer" but nonetheless raising Philips' and PolyTech's plan to continue using ester foam. <sup>418</sup>
Philips		May 22, 2018	Communications to prepare Philips' Biological Risk Assessment document, which was deemed "inadequate" by the FDA because it did not "accurately reflect known data" about PE-PUR foam degradation in Trilogy ventilator devices. <sup>419</sup>
Philips		May 2018	Communications to prepare Philips' Health Hazard Evaluation, ER22227646, which was deemed "inadequate" by the FDA because it did not "accurately reflect known data" about PE-PUR foam degradation in Trilogy ventilator devices.
Philips		June 2018	Communications to close CAPA INV 0988 related to Trilogy Devices without reference to other CPAP and

<sup>417</sup> See Email from Vince Testa at Philips to Bonnie Peterson at PolyTech dated 4/20/2018, forwarded from Bob Marsh at PolyTech to Lee Lawler at Burnett on 4/23/2018 (Lawler Aff. Exh. D) (attached hereto as Exhibit "139"), at WTB 000054-55.

<sup>418</sup> See Email correspondence by and among Vince Testa at Philips, Bob Marsh and Bonnie Peterson at PolyTech, and Lee Lawler at Burnett (Lawler Aff. Exh. G) (attached hereto as Exhibit "140"), at WTB 000061-65.

<sup>419</sup> 483 Report (Exhibit "5" hereto), at 12.

			BiPAP devices, including the Recalled Devices despite knowledge of consumer complaints of foam degradation in those devices.
Philips		August 24, 2018	Intra-company email amongst Philips personnel discussing testing that confirmed that the affected foam breaks down in high heat and high humidity environments, which concurred with Trilogy ventilator related complaints received.
Philips		December 12, 2018	Communications transmitting test results that acknowledged a “problem of degradation” in PE-PUR foam in Trilogy devices as a result of field reports/complaints, following which “no further design change, corrective action, or field correction was conducted” for the Recalled Devices for at least three years. <sup>420</sup>
Philips		June 2019	Documents and communications for inadequate formal CAPA 7211 investigation that excluded known medical device reports and complaints.
Philips		April 26, 2021	Press release admitting to serious health risks of the Recalled Devices but misleadingly casting blame on other “factors” such as ozone cleaners.

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<sup>420</sup> 483 Report (Exhibit “5” hereto), at 5.

520. Each of the predicate acts detailed above had the common purpose of generating significant revenue and profits for the RICO Defendants from the sale of Recalled Devices. This was accomplished by concealing from patients, prescribers, third-party payors, and the FDA the true health risks and the safety defect associated with the Recalled Devices and their PE-PUR foam. Further, this common purpose was served by the above-described instances of RICO Defendants sharing information and evidence about the Defect among the Enterprise. This sharing of information allowed for the RICO Defendants to coordinate in their actions and efforts to conceal.

521. The RICO Defendants' pattern of racketeering activity alleged herein and the Philips-PolyTech Enterprise are separate and distinct from each other. Likewise, the RICO Defendants are distinct from the Enterprise.

522. The racketeering activities conducted by the RICO Defendants amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators, and Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by the RICO Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators and Plaintiffs. The RICO Defendants have engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Enterprise.

523. Each of the RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

524. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted various unlawful activities, each conducted with the common purpose of obtaining revenue from the marketing and sale of the defective Recalled Devices. The predicate acts also had the same or similar results, participants, targeted pool of victims, and methods of commission. The predicate acts were related and not isolated.

e. **The RICO Defendants Advanced Their Fraudulent Scheme By Concealing Material Information About Serious Safety Risks Posed By The Recalled Devices That They Had A Duty To Disclose.**

525. The uses of mail and wire described above violated the mail and wire fraud statutes because they furthered a fraudulent scheme to mislead consumers, prescribers, third party payors, hospitals, and the FDA about the Recalled Devices.

526. In addition, these same uses of mail and wire were illegal because, when they sent or caused to be sent, RICO Defendants had duties to disclose the health and safety risks associated with the Recalled Devices. The RICO Defendants failed to disclose this critical information in order to advance their scheme.

527. For years, the RICO Defendants each knew of the risks and safety concerns in the Recalled Devices. Specifically, Philips and PolyTech knew no later than 2015—meaning, at best, six years before a public recall announcement—about foam degradation issues in PE-PUR foam in the field. To further the goals of the Philips-PolyTech Enterprise and to their mutual monetary gain, the RICO Defendants failed to disclose the existence, scope, and material safety risks of the Defect in the Recalled Devices, and continued to manufacture and sell them for years in spite of that knowledge.



528. The RICO Defendants' careful efforts to conceal the risks of the Recalled Devices were critically important to the viability of their scheme. A decision by any one RICO Defendant to tell the truth about the Defect would have been an existential threat to the Enterprise. Instead, each RICO Defendant kept key information about the risks of the Recalled Devices and known issues hidden for years. This omission of material facts about the Defect occurred because it advanced the RICO Defendants' scheme to sell defective Recalled Devices and avoid costly recalls and reputational harms.

529. The RICO Defendants' failure to disclose the known safety risks given the Defect in the Recalled Devices violated several independent duties to disclose.

- a. As a medical device manufacturer, Philips had a duty to disclose material facts about the safety risks of its devices to physicians, patients, and the FDA. This includes Philips' statutory and regulatory duties pursuant to 21 U.S.C. § 352 (FDCA); 21 C.F.R. § 820.70 and 21 C.F.R. § 803.
- b. The RICO Defendants also each had a duty to disclose the Defect in the Recalled Devices because of their exclusive knowledge and far superior information in their possession. The RICO Defendants knew about the risks to users of the Recalled Devices due to the PE-PUR foam, which they gathered through their exclusive access to information about their design, development, and testing, and through their confidential and proprietary investigations following consumer complaints. Plaintiffs, by contrast, lack the sophisticated expertise that would be necessary to discover the Defect and its implications on their own.

- c. The RICO Defendants' affirmative steps to conceal the Defect deprived Plaintiffs and Class Members from an opportunity that otherwise could have led to their discovery of the truth. Philips and PolyTech also each had a duty to disclose because of the actions they took to conceal the Defect which was a material fact, in the Recalled Devices. Philips acted to suppress the truth including when it inappropriately limited and closed its CAPA investigations (thus avoiding a written record), omitted relevant data from its Biological Risk Assessments, and attempted to blame independent factors such as ozone cleaners for the Defect. PolyTech, for its part, suppressed the truth when it corresponded with Burnett about the known risks of PE-PUR foam and took no action, instead continuing to supply the foam to Philips for use in the Recalled Devices.
- d. Finally, Philips affirmatively disclosed information about the Recalled Devices such as the information discussed in ¶¶ 214 and 215 above. Because Philips opted to make these representations, and because it knew other information about the Recalled Devices that made those representations misleading or untrue, Philips was under a separate duty to disclose the full truth about the Defect that materially qualified the information it provided.

530. The RICO Defendants knew and intended that Plaintiffs would rely on their and the other Enterprise members' material omissions when they paid for and used the Recalled Devices. Plaintiffs' reliance on this concealment is demonstrated by the fact that they paid

money for defective Recalled Devices that never should have been introduced into the U.S. stream of commerce.

**f. The Philips-PolyTech Enterprise's Pattern Of Racketeering Injured Plaintiffs And The Nationwide Class Members In Their Business Or Property When They Paid For Defective Recalled Devices.**

531. Plaintiffs and Nationwide Class members are “person[s] injured in his or her business or property” by reason of the Enterprise’s RICO violations, within the meaning of U.S.C. § 1964(c). Plaintiffs and Nationwide Class members are entitled to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys’ fees pursuant to 18 U.S.C. § 1964(c).

532. Because of the Philips-PolyTech Enterprise’s pattern of racketeering activity, Plaintiffs and Nationwide Class members have been injured in their business and/or property by paying for or reimbursing for, in whole or part, Recalled Devices with an undisclosed safety defect. Because of this Defect, Plaintiffs paid money for or reimbursed payment for, in whole or part, Recalled Devices that had no actual value at the time of purchase.

533. As such, the Philips-PolyTech Enterprise directly or indirectly obtained money from Plaintiffs and the Nationwide Class by means of materially false or fraudulent misrepresentations and omissions of material facts. Had the Plaintiffs and Class members known what the RICO Defendants knew about the Recalled Devices, they would not have paid for or reimbursed payment for, in whole or part, the Recalled Devices.

534. The RICO Defendants’ violations of law and their pattern of racketeering activity directly and proximately caused injury to Plaintiffs’ and Nationwide Class members’ business and property. The RICO Defendants’ pattern of racketeering activity logically, substantially, and foreseeably caused third party payors, hospitals, and consumers to pay for or reimburse payment

for, in whole or part, the Recalled Devices. The injuries suffered by the Plaintiffs and Nationwide Class members' injuries were not unexpected, unforeseen, or independent. Rather, the RICO Defendants knew that the Recalled Devices were defective and unsafe. Regardless of these known risks, the RICO Defendants used mail and wires to carry out their scheme of deception, thereby reaping increased profits.

535. Had the RICO Defendants disclosed their knowledge of the Defect in the Recalled Devices and informed the FDA and the public, Plaintiffs would have learned of the disclosure and made informed decisions about their health.

- a. Had any of the RICO Defendants disclosed the Recalled Devices' defective condition to the FDA, the FDA would have considered the information material, and would have informed consumers. This is evidenced by the FDA's classification of the recall as Class I after Philips ultimately disclosed the Defect it had long concealed.
- b. Had the RICO Defendants disclosed the Recalled Devices' defective condition to the public, either through press releases, their websites, or in any other public forum, Plaintiffs and Nationwide Class members would have learned of the Defect. Further, given the seriousness of the information and the number of devices impacted, the news media and consumer forums would have published this information.
- c. Had the RICO Defendants disclosed the defective nature of the Recalled Devices via any of the channels typically used to advertise, market, and/or communicate information about those devices, Plaintiffs and Nationwide Class members would have learned about the Defect.

536. The Enterprise's misleading statements and omissions to the FDA and to prescribers were essential to the scheme. The FDA would have considered information about the defective PE-PUR foam material (as evidenced by its Class I classification of the ongoing recall), and prescribers would not have prescribed dangerous and defective breathing machines to their patients. At the very least, the RICO Defendants' misleading statements delayed the FDA's broader investigation of the Recalled Devices.

537. In the case of fraud on third parties (*i.e.*, the FDA and prescribers), the RICO Defendants' omissions and misrepresentations to third parties facilitated Plaintiffs' and Nationwide Class members' purchase or lease of unsafe products that should not have been on the market. The FDA and prescribers have not suffered any direct injury as a result of the RICO Defendants' violations.

538. As the purchasers and lessees (and typically users) of the Recalled Devices, Plaintiffs and the Nationwide Class are the parties most affected by the RICO Defendants' misconduct. The RICO Defendants knew that their concealment of the risks would cause Plaintiffs and the Nationwide Class to pay for or reimburse payment for the Recalled Devices and to the extent they are the users of the Recalled Devices, to suffer the attendant harms and safety risks of breathing through machines with potentially toxic foam.

539. In light of the above, Plaintiffs and the Nationwide Class members seek actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq.*

**COUNT 2 – VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT  
ORGANIZATIONS ACT, 18 U.S.C. § 1962(D), AGAINST PHILIPS AND POLYTECH  
On behalf of the Nationwide Class and all Subclasses<sup>421</sup>**

540. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

541. This claim is brought by Plaintiffs against the Philips Defendants and the PolyTech Defendants (within this claim, the “RICO Defendant(s)”) for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964, for violations of 18 U.S.C. § 1961, *et seq.*

542. Plaintiffs are each a “person,” as that term is defined in 18 U.S.C. § 1961(3), and have standing to sue under 18 U.S.C. § 1964(c) as they were and are injured in their business and/or property “by reason of” the RICO Act violations described herein.

543. It is unlawful “for any person to conspire to violate” 18 U.S.C. § 1962(c). *See* 18 U.S.C. § 1962(d). A defendant who “agreed to facilitate a scheme” violates section 1962(d) even if he “does not himself commit or agree to commit the two or more predicate acts requisite to the underlying offense.” *Salinas v. United States*, 522 U.S. 52, 65-66 (1997).

544. The RICO Defendants have undertaken the practices described herein as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the RICO Defendants agreed to facilitate the operation of the Enterprise through a pattern of racketeering in violation of 18 U.S.C. § 1962(c), as described herein. The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the Enterprise described in the previous Count through a pattern of racketeering activity. The RICO Defendants conspired with the Enterprise participants to manufacture, sell, and profit from the Recalled Devices while

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<sup>421</sup> Plaintiffs will submit a RICO case statement pursuant to Local R. Civ. P. 7.1.B within 14 days.

concealing their health and safety risks. The conspiracy is coterminous with the time period in which the Enterprise has existed, beginning no later than 2015 and continuing to this day.

545. The words, actions, or interdependence of activities of each RICO Defendant supports the inference of their agreement. Put another way, the RICO Defendants' agreement is evidenced by their predicate acts and direct participation in the control and operation of the Enterprise, as detailed above in relation to the RICO Defendants' substantive violation of Section 1962(c).

546. The RICO Defendants' acts in furtherance of the conspiracy include each of the predicate acts underlying the RICO Defendants' violations of Section 1962(c), as described above. Various other persons, firms, and corporations, including third-party entities and individuals not named as Defendants in this Complaint, have participated as co-conspirators with the members of the Enterprise in these offenses and furthered the conspiracy to conceal the health and safety risks in the Recalled Devices to increase or maintain revenue from their sale.

547. The success of the Enterprise's fraudulent scheme depended upon the RICO Defendants' cooperation and agreement. These companies had to maintain strict confidentiality about the health and safety risks in the Recalled Devices or the scheme to continue. Even after learning about the health and safety risks associated with the PE-PUR foam used in the Recalled Devices, PolyTech continued to obtain the foam from Burnett and prepare it for use in the Recalled Devices. When doing so, PolyTech knew that Philips would manufacture and sell the Recalled Devices to Plaintiffs and the Nationwide Class without disclosing those risks. Likewise, Philips, with knowledge of the Defect, continued to place orders that would cause PolyTech to obtain and ship PE-PUR foam for use in the recalled devices.

548. Philips depended upon PolyTech for the sourcing, cutting, and acquisition of the PE-PUR foam for the Recalled Devices, and for coordinating with Burnett to do so. On the other hand, PolyTech depended upon Philips for a viable path to profit from sale of the Recalled Devices. This interdependence evidences the agreement to further the fraudulent scheme.

549. Where a RICO Defendant did not commit a predicate act itself, it is sufficient if it was aware of the essential nature and scope of the Enterprise such that it agreed to the commission of the foreseeable predicate acts to advance the Enterprise's goals. The actions detailed above and throughout the Complaint as to each member of the Enterprise were foreseeable to the other members of the Philips-PolyTech Enterprise given their direct relationship to and furtherance of the common goals of the scheme.

550. Philips and PolyTech each violated 18 U.S.C. § 1962(d) and injured the business or property of Plaintiffs and the Nationwide Class. The RICO Defendants' violations of 18 U.S.C. § 1962(d) caused the same injuries and damages described in the prior Count. This Count incorporates by reference the allegations as to injury, damages, and causation from the prior Count. Plaintiffs claim damages for themselves and the Nationwide Class members under 18 U.S.C. § 1964(c).

**COUNT 3 – NEGLIGENT FAILURE TO RECALL/NEGLIGENT RECALL**  
**On Behalf of the Nationwide Class and all Subclasses**

551. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

552. This claim is brought against the Philips Defendants.

553. Despite being aware of the Defect in the Recalled Devices as far back as 2008, Philips did not initiate a recall of the Recalled Devices until June 14, 2021.



554. At all times relevant hereto, Philips manufactured, marketed, distributed, and sold the Recalled Devices.

555. As set forth in detail above, as far back as 2008 (and in no event later than 2015), Philips knew or reasonably should have known that the Recalled Devices were defective and exposed users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam in the Recalled Devices.

556. Despite that knowledge, Philips did not attempt to recall or retrofit the Recalled Devices prior to June 14, 2021, long after any reasonable manufacturer, distributor and/or seller under the same circumstances would have instituted a recall or retrofitted the Recalled Devices.

557. Because of the delay in instituting a recall, Plaintiffs continued to pay for and reimburse payment for the Recalled Devices when, without their knowledge, users were being exposed to substantial health risks.

558. Had Philips instituted a recall when the risks to potential users of using the Recalled Devices were first made clear, Plaintiffs would have not paid for or reimbursed payment for the defective devices and would have sought alternative methods to treat their breathing-related illnesses.

559. Philips was aware that Plaintiffs would make such a choice. That is why Philips waited until it announced the launch of the DreamStation 2, which does not contain PE-PUR foam, before it publicly disclosed that its previous generation of DreamStation products and other Recalled Devices posed serious health risks to users, and before Philips finally instituted a recall.

560. Even after Philips finally announced it was instituting a voluntary recall of the Recalled Devices, it implemented the Recall negligently.

561. Royal Philips took charge of and responsibility for the Recall. Royal Philips has interfaced with regulatory agencies in the U.S. and worldwide, but has not adequately notified users and their doctors about the recall or the options for obtaining a replacement device.

562. First, when the Recall was announced on June 14, 2021, Philips did not adequately provide notice to users or their doctors about the risks of using the Recalled Devices, nor did Philips offer users of the Recalled Devices any option for a replacement device. In fact, the FDA issued a Notification Order to Philips under § 518(a) of the FDCA, documenting that the FDA “on multiple occasions has informed Philips that FDA was concerned that Philips’ efforts to notify patients and consumers, healthcare providers, and consignees regarding the recall have been insufficient,” and has expressed concern that “it is likely that a significant portion of patients and consumers using the Recalled Products are unaware of the health risks presented by those products.”<sup>422</sup>

563. Then, when Philips received authorization from the FDA to begin a repair and/or replacement process for affected DreamStation devices in the United States, Philips estimated that it would take a year to complete the program. Philips was aware that this time frame was untenable for patients, many of whom relied on the machines to treat medical conditions.

564. In addition, DreamStation customers were not given any specifics as to how the replacement program would work nor were they told when they might receive a replacement device (a significant factor for users who, again, relied on the machines for medical conditions) nor were their treating physicians given any meaningful guidance by Philips.

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<sup>422</sup> 518(a) Notification Order (Exhibit “136” hereto), at 6.

565. Still, the repair/replacement program only applied to affected DreamStation devices and did not impact any of the other Recalled Devices. Later, Philips instituted a repair program for the Trilogy devices, which has only just recently begun.

566. Despite the estimated one-year timeline originally announced by Philips to replace recalled DreamStation devices, Philips has not performed the Recall according to its own projections, and many users are still waiting for repaired or replaced devices.

567. In issuing a voluntary recall, Philips assumed duties to exercise reasonable care in issuing and implementing the Recall. Philips' conduct constitutes a breach of its duties by failing to adequately warn and notify users of the risks of using the Recalled Devices and failing to promptly replace the Recalled Devices.

568. As a direct result of Philips' breach of duty, Plaintiffs were damaged and continue to be damaged by having to stop using a Recalled Device that is a treatment for a health condition, pay money out of pocket to replace that Recalled Device, or continue using a defective Recalled Device.

569. In addition, as a direct and proximate cause of Philips' breach of duty, Plaintiffs may suffer additional serious and debilitating illnesses or injuries, including various cancers, in the future as a result of continued exposure to the Foam Toxins.

570. Plaintiffs demand judgment against Philips and request in this Complaint compensatory damages, punitive damages, interest, costs of suit, attorneys' fees, and such other relief as the Court deems equitable and just. Separately, Plaintiffs are seeking medical monitoring damages and relief pursuant to the Court's scheduling order for the filing of amended consolidated class complaints for economic losses and medical monitoring and an amended Master Long Form Complaint for personal injuries (ECF 768).

**COUNT 4 – BREACH OF EXPRESS WARRANTY**  
**On behalf of the Nationwide Class and all Subclasses**

571. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

572. This claim is brought against the Philips Defendants.

573. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. When they sold the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would be exposed to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam.

574. At the time of sale, Philips provided a User Manual with its CPAP, BiPAP, and ventilator devices. Royal Philips owns the copyright to all, or most, of those User Manuals.

575. Philips' User Manuals for the Recalled Devices contained an express warranty providing that the Recalled Devices "shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale."<sup>423</sup>

576. Philips breached this express warranty in connection with the sale and distribution of Recalled Devices. At the point of sale, the Recalled Devices, while appearing normal, contained latent defects as set forth in more detail above, rendering them unsuitable and unsafe for personal use.

577. Plaintiffs and the Class reasonably expected, at the time of purchase, lease, or reimbursement, that the Recalled Devices were safe for their ordinary and intended use. Had

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<sup>423</sup> See, e.g., Warranty Exemplars: DreamStation (Exhibit "47" hereto), at 29; REMstar SE (Exhibit "48" hereto), at 21; Trilogy 100 (Exhibit "49" hereto), at 163.

Plaintiffs and the Class known the Recalled Devices were defective, unsafe for use, and exposed them to the Foam Toxins, they would not have purchased, leased, or reimbursed payment for them.

578. Philips has breached its warranty and refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices.

579. To the extent privity may be required, Plaintiffs and the Class can establish privity with Philips or alternatively, Plaintiffs can establish that they fall into an exception to a privity requirement.

580. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

581. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

582. The Recalled Devices are medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

583. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

584. In addition, any purported durational limit to the warranties would be procedurally and substantively unconscionable and otherwise unenforceable.

585. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the warranties, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was drafted by Philips unilaterally,

and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device on a “take it or leave it” basis. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

586. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties’ relative bargaining power, which Philips used to craft a warranty that unreasonably favors it over the Class. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit were enforceable, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the warranties in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect prior to or at the point of purchasing the Recalled Devices.

587. Relatedly, due to Philips’ knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the warranties would be tolled or waived. Philips’ affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who did not have notice of or the ability to detect the latent defect, to purchase the Recalled Devices that purportedly had the temporal limitation on the warranties.

588. In addition, any attempt by Philips to limit the term of the warranties should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

589. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for over a year.

590. As a direct and proximate result of Philips' breach of its express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

591. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected, at the time of purchase, that the Recalled Devices were safe for their ordinary and intended use.

**COUNT 5 – BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY**  
**On behalf of the Nationwide Class and all Subclasses**

592. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

593. This claim is brought against the Philips Defendants.

594. The implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code § 7-2-314, *et seq.*; Alaska Stat. § 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. § 47-2314, *et seq.*; Ark. Code Ann. § 4-2-314, *et seq.*; Cal. Com. Code § 2314, *et seq.*; Colo. Rev. Stat. § 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. § 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, § 2-314, *et seq.*; D.C. Code Ann. § 28:2-314, *et seq.*; Fla. Stat. Ann. § 672.314, *et seq.*; O.C.G.A. § 11-2-314, *et seq.*; Haw. Rev. Stat. § 490:2-314, *et seq.*; Idaho Code § 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. § 26-1-2-314, *et seq.*; Iowa Code Ann. § 554.2314, *et seq.*; Kan. Stat. Ann. § 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. § 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, § 2-

314, *et seq.*; Md. Code Ann., Com. Law § 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, § 2-314, *et seq.*; Mich. Comp. Laws Ann. § 440.2314, *et seq.*; Minn. Stat. Ann. § 336.2-314, *et seq.*; Miss. Code Ann. § 75-2-314, *et seq.*; Mo. Rev. Stat. § 400.2-314, *et seq.*; Mont. Code Ann. § 30-2-314, *et seq.*; Neb. Rev. Stat. § 2-314, *et seq.*; Nev. Rev. Stat. § 104.2314, *et seq.*; N.H. Rev. Stat. Ann. § 382-A:2-314, *et seq.*; N.J. Stat. Ann. § 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law § 2-314, *et seq.*; N.C. Gen. Stat. Ann. § 25-2-314, *et seq.*; N.D. Cent. Code § 41-02-31, *et seq.*; Ohio Rev. Code Ann. § 1302.27, *et seq.*; Okla. Stat. tit. 12A, § 2-314, *et seq.*; Or. Rev. Stat. § 72.3140, *et seq.*; 13 Pa. Stat. Ann. § 2314, *et seq.*; R.I. Gen. Laws § 6A-2-314, *et seq.*; S.C. Code Ann. § 36-2-314, *et seq.*; S.D. Codified Laws § 57A-2-314, *et seq.*; Tenn. Code Ann. § 47-2-314, *et seq.*; Tex. Bus. & Com. Code § 2.314, *et seq.*; Utah Code Ann. § 70A-2-314, *et seq.*; Va. Code Ann. § 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, § 2-314, *et seq.*; Wash. Rev. Code § 62A.2-314, *et seq.*; W. Va. Code § 46-2-314, *et seq.*; Wis. Stat. Ann. § 402.314, *et seq.*; and Wyo. Stat. Ann. § 34.1-2-314, *et seq.*

595. Philips has, at all times, been a merchant with respect to the products which were sold to Plaintiffs and the Class, under U.C.C. §§ 2-104 and 2-314, as codified in each state; and was in the business of selling such products.

596. Pursuant to U.C.C. § 2-314, as codified in each state, each Recalled Device sold by Philips comes with an implied warranty that it will be merchantable and fit for the ordinary purpose for which it would be used.

597. The ordinary intended purpose of the Recalled Devices—and the purpose for which they were marketed, promoted, and sold—was to help people breathe. The Recalled Devices were not fit for that use—or any other use—because using the Recalled Device for breathing assistance exposed the user to Foam Toxins as a result of the degradation and off-



gassing of the PE-PUR foam. When used as intended, the Recalled Devices were unsuitable and unsafe for personal use.

598. Philips breached its implied warranty of merchantability because the Recalled Devices were not in merchantable condition when sold, were defective when sold, and/or did not possess even the most basic degree of fitness for ordinary use.

599. Plaintiffs and the members of the Class were injured as a direct and proximate result of Philips' breach of its implied warranty of merchantability because, had they been aware of the unmerchantable condition of the Recalled Devices, they would not have purchased or leased them nor would they have paid for or reimbursed payment for them.

600. To the extent that privity may be required, Plaintiffs and the members of the Class can establish privity with Philips, or, alternatively, can establish that they fall into an exception to a privity requirement.

601. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

602. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

603. The Recalled Devices are products such medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

604. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

605. In addition, any purported durational limit to the implied warranty of merchantability would be procedurally and substantively unconscionable and otherwise unenforceable.

606. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the implied warranty of merchantability, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was drafted by Philips, without any input or consent from Plaintiffs and the Class, and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

607. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties' relative bargaining power. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit existed, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the implied warranty of merchantability in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect prior to or at the point of purchasing the Recalled Devices.

608. Relatedly, due to Philips' knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the

implied warranty of merchantability would be tolled or waived. Defendants' affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who did not have notice of or the ability to detect the latent defect, to purchase the Recalled Devices that purportedly had the temporal limitation on the implied warranty of merchantability in place.

609. In addition, any attempt by Philips to limit the term of the implied warranty of merchantability should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

610. Plaintiffs are not required to give notice to Philips, a remote manufacturer, and Philips has had notice of the type and source of claims in this matter for over a year. Further, at a minimum on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements

611. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected, at the time of purchase, lease, or reimbursement, that the Recalled Devices were safe for their ordinary and intended use.

612. As a direct and proximate result of Philips' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

**COUNT 6 – BREACH OF THE IMPLIED WARRANTY OF USABILITY**  
**On behalf of the Nationwide Class and all Subclasses**

613. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

614. This claim is brought against the Philips Defendants.

615. The implied warranty of usability arises under U.C.C. § 2-314 which has been codified in each state. *See, e.g.*, Ala. Code § 7-2-314, *et seq.*; Alaska Stat. § 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. § 47-2314, *et seq.*; Ark. Code Ann. § 4-2-314, *et seq.*; Cal. Com. Code § 2314, *et seq.*; Colo. Rev. Stat. § 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. § 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, § 2-314, *et seq.*; D.C. Code Ann. § 28:2-314, *et seq.*; Fla. Stat. Ann. § 672.314, *et seq.*; O.C.G.A. § 11-2-314, *et seq.*; Haw. Rev. Stat. § 490:2-314, *et seq.*; Idaho Code § 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. § 26-1-2-314, *et seq.*; Iowa Code Ann. § 554.2314, *et seq.*; Kan. Stat. Ann. § 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. § 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, § 2-314, *et seq.*; Md. Code Ann., Com. Law § 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, § 2-314, *et seq.*; Mich. Comp. Laws Ann. § 440.2314, *et seq.*; Minn. Stat. Ann. § 336.2-314, *et seq.*; Miss. Code Ann. § 75-2-314, *et seq.*; Mo. Rev. Stat. § 400.2-314, *et seq.*; Mont. Code Ann. § 30-2-314, *et seq.*; Neb. Rev. Stat. § 2-314, *et seq.*; Nev. Rev. Stat. § 104.2314, *et seq.*; N.H. Rev. Stat. Ann. § 382-A:2-314, *et seq.*; N.J. Stat. Ann. § 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law § 2-314, *et seq.*; N.C. Gen. Stat. Ann. § 25-2-314, *et seq.*; N.D. Cent. Code § 41-02-31, *et seq.*; Ohio Rev. Code Ann. § 1302.27, *et seq.*; Okla. Stat. tit. 12A, § 2-314, *et seq.*; Or. Rev. Stat. § 72.3140, *et seq.*; 13 Pa. Stat. Ann. § 2314, *et seq.*; R.I. Gen. Laws § 6A-2-314, *et seq.*; S.C. Code Ann. § 36-2-314, *et seq.*; S.D. Codified Laws § 57A-2-314, *et seq.*; Tenn. Code Ann. § 47-2-314, *et seq.*; Tex. Bus. & Com. Code § 2.314, *et seq.*; Utah Code Ann. § 70A-2-314, *et seq.*; Va. Code Ann. § 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, § 2-314, *et seq.*; Wash. Rev. Code § 62A.2-314, *et seq.*; W. Va. Code § 46-2-314, *et seq.*; Wis. Stat. Ann. § 402.314, *et seq.*; and Wyo. Stat. Ann. § 34.1-2-314, *et seq.*

616. Philips has, at all times, been a merchant with respect to the products which were sold to Plaintiffs and the Class, under U.C.C. §§ 2-104 and 2-314, as codified in each state; and was in the business of selling such products.

617. By operation of law, Philips, as the manufacturer of the Recalled Devices and as the providers of a limited warranty for the Recalled Devices, impliedly warranted to Plaintiffs and the Class that the Recalled Devices were usable for their ordinary and intended use.

618. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

619. Through usage of trade, manufacturers of medical devices, such as the Recalled Devices, impliedly warrant that their products are usable for the end consumer.

620. The ordinary intended use of the Recalled Devices was to help people breathe. The Recalled Devices were not fit for that use—or any other use—because using the Recalled Device for breathing assistance exposed the user to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. When used for their ordinary and intended use, the Recalled Devices were unsuitable and unsafe, and, thus, adulterated.

621. Philips breached its implied warranty of usability because the Recalled Devices were not usable for their ordinary and intended use and were not usable for the end consumer. At the point of sale, the Recalled Devices while appearing normal—contained the Defect rendering them unusable.

622. Philips, its agents and employees knew, or should have known, that the Recalled Devices suffered from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

623. Philips' Recall announcement instructed Class members to not use Recalled Devices because of the health risks illustrating that the Recalled Devices are unusable and worthless.

624. Philips has refused to provide appropriate warranty relief notwithstanding the risks of using the Recalled Devices. Plaintiffs and the Class reasonably expected, at the time of purchase, lease, or reimbursement, that the Recalled Devices were usable for their ordinary and intended use.

625. Plaintiffs and the members of the Class were injured as a direct and proximate result of Philips' breach of its implied warranty of usability because, had they been aware that the Recalled Devices were not usable as a breathing device, they would not have purchased, leased, or reimbursed payment for them nor would they have paid for or reimbursed payment for them.

626. To the extent privity may be required, Plaintiffs and the members of the Class can establish privity with Philips, or, alternatively, can establish that they fall into an exception to a privity requirement.

627. Plaintiffs and the members of the Class relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

628. Plaintiffs and the members of the Class were foreseeable and intended third-party beneficiaries of Philips' sale of the Recalled Devices, and/or of contracts between Philips and the distributors or sellers of the Recalled Devices.

629. The Recalled Devices are products such as medical devices that affect human health and life; and therefore, they implicate the broad public policy of protecting human health and life.

630. Enforcement of a privity requirement would unfairly prejudice Plaintiffs and the members of the Class, who relied on Philips' warranties and dealt directly with Philips through the exchange of warranty and recall information.

631. In addition, any purported durational limit to the implied warranty of usability would be procedurally and substantively unconscionable and otherwise unenforceable.

632. An attempted durational limit would be procedurally unconscionable because Philips unilaterally imposed the time limitation on the implied warranty of usability, without affording Plaintiffs and the Class any bargaining authority. Indeed, the limitation was drafted by Philips, without any input or consent from Plaintiffs and the Class, and it was presented to Plaintiffs and the Class as a settled term in the User Manual issued for each Recalled Device. As such, Plaintiffs and the Class had no meaningful choice in setting any temporal limitation on the warranty.

633. Such a limitation would be substantively unconscionable because there was a substantial disparity in the parties' relative bargaining power. As Plaintiffs allege, prior to and at the time it sold the Recalled Devices to Plaintiffs and the Class, Philips was aware of the latent defect regarding PE-PUR foam degradation in the Recalled Devices. Yet, Philips suppressed information concerning the latent defect from Plaintiffs and the Class. If a durational limit existed, it would mean Philips had abused its superior knowledge of the Defect to manipulate the temporal limits of the implied warranty of usability in such a manner so that it could avoid coverage relating to the latent defect while it continued manufacturing and selling the Recalled Devices containing PE-PUR foam, including to Plaintiff and the Class. Plaintiffs and the Class had no notice or ability to detect the latent defect prior to or at the point of purchasing the Recalled Devices.

634. Relatedly, due to Philips’ knowing concealment of facts and information concerning the latent defect in the Recalled Devices, any purported durational limitation on the implied warranty of usability would be tolled or waived. Defendants’ affirmative acts of concealment were designed to prevent any inquiry concerning the Recalled Devices and to induce Plaintiffs and the Class, who did not have notice of or the ability to detect the latent defect, to purchase the Recalled Devices that purportedly had the temporal limitation on the implied warranty of usability in place.

635. In addition, any attempt by Philips to limit the term of the implied warranty of usability should not be enforced given that the language purporting to set forth the limitation was not presented to Plaintiffs and the Class in a clear and conspicuous manner.

636. Plaintiffs are not required to give notice to Philips, a remote manufacturer and Philips has had notice of the type and source of claims in this matter for over a year. Further, at a minimum on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements.

637. As a direct and proximate result of Philips’ breach of the implied warranty of usability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

**COUNT 7 – VIOLATIONS OF MAGNUSON-MOSS FEDERAL WARRANTY ACT**  
**15 U.S.C. § 2301, *et seq.***  
**On behalf of the Nationwide Class and all Subclasses**

638. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

639. This claim is brought against the Philips Defendants.

640. The Recalled Devices constitute “consumer products” as defined in 15 U.S.C. §



2301(1).

641. The Recalled Devices are tangible personal property owned by Plaintiffs and the members of the Class.

642. The Recalled Devices were distributed in commerce.

643. The Recalled Devices are normally used for personal and/or household purposes, in that they are used by individual persons for breathing assistance, often in the home. This is a personal purpose because it is a purpose related to the person or the body.

644. Plaintiffs and the members of the Class are “consumers” as defined in 15 U.S.C. § 2301(3).

645. Plaintiffs and the members of the Class are buyers or lessors of the Recalled Devices, and/or are persons to whom the Recalled Devices were transferred during the duration of implied and written warranties applicable to the Recalled Devices, and/or are persons entitled by the terms of those warranties, and by applicable State law, to enforce against Philips the obligations of the warranties.

646. Philips is a “supplier” of the Recalled Devices as defined in 15 U.S.C. § 2301(4).

647. Philips is or was engaged in the business of making the Recalled Devices, which are consumer products, and of making other consumer products, directly or indirectly available to consumers, including through its subsidiaries and third-party distributors.

648. Philips is a “warrantor” as defined in 15 U.S.C. § 2301(5).

649. Philips is a supplier or other person: (a) who gave or offered to give a written warranty applicable to the Recalled Devices; and/or (b) who is or may be obligated under an implied warranty applicable to the Recalled Devices.

650. As discussed above, Philips made numerous express and implied warranties to

Plaintiffs and members of the Class with respect to the Recalled Devices.

651. The warranties made by Philips pertained to consumer products costing the consumer more than five dollars, *see* 15 U.S.C. § 2302(e).

652. Plaintiffs and the members of the Class invoke federal jurisdiction for the claims stated under this Count pursuant to the Class Action Fairness Act.

653. The Recalled Devices were defective when they came off Philips' assembly lines and at all subsequent times (including at the times of sale and/or delivery to Plaintiffs and the members of the Class) because the defective design and the degradation and off-gassing of the PE-PUR foam made them dangerously unsafe.

654. As a result, the Recalled Devices were worth nothing at the time of their sales.

655. Plaintiffs and the members of the Class would not have purchased or accepted the Recalled Devices had they known the machines were dangerously defective.

656. Philips violated the Magnuson-Moss Federal Warranty Act by failing to comply with the express warranties they made to Plaintiffs and the members of the Class. Philips violated the Magnuson-Moss Federal Warranty Act by failing to comply with the implied warranties they made to Plaintiffs and the members of the Class.

657. Plaintiffs and the other members of the Class need not have given notice of the defects to Philips and an opportunity for Philips to comply with their warranty obligations prior to the filing of this suit because Plaintiffs may give such notice to Philips on their own behalf and on behalf of the Class after class certification pursuant to 15 U.S.C. § 2310(e).

658. Based on the facts alleged here, any durational limit to the warranties that would otherwise bar the Magnuson-Moss Federal Warranty Act claims in this Count are procedurally and substantively unconscionable and otherwise unenforceable under federal law and applicable

state common law.

659. Based on the facts alleged here, any durational limit to the warranties that would otherwise bar the claims in this Count is tolled under equitable doctrines.

660. Plaintiffs and the members of the Class sustained injuries and damages as a proximate result of Philips' violation of its express and implied warranties, and are entitled to legal and equitable relief against Philips, including compensatory damages consisting of: the difference between the values of the Recalled Devices as warranted (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and rescission or other miscellaneous incidental and consequential damages. In addition, pursuant to 15 U.S.C. § 2310(d)(2), Plaintiffs and the other members of the Class are entitled to recover a sum equal to the aggregate amount of costs and expenses (including attorneys' fees based on actual time expended) determined by the Court to have been reasonably incurred by them in connection with the commencement and prosecution of this action.

**COUNT 8 – COMMON LAW FRAUD**  
**On Behalf of the Nationwide Class and all Subclasses**

661. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

662. This claim is brought against the Philips Defendants.

663. At all relevant times, Philips knew that the Recalled Devices posed serious health risks to users.

664. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as

they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers, including Plaintiffs, Class members, and their physicians, because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

665. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

666. Philips concealed from Plaintiffs and Class members and failed to disclose to them material information regarding the serious health risks posed to users of the Recalled Devices by, among other things, failing to include material information in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures.

667. Philips was under a duty to disclose to, among others, Plaintiffs, Class members, and their physicians, the serious health risks posed to users of the Recalled Devices because: (a) Philips was in a superior position to know the risks associated with the use of the Recalled Devices; (b) Philips was in a superior position to determine whether or not to disclose or conceal information regarding the Recalled Devices in its packaging, labels, advertising, websites, and other communications and disclosures; (c) Philips had a duty to fully disclose all facts related to the serious health risks to users posed by the Recalled Devices; (d) Philips knew that Plaintiffs, Class members and their physicians could not reasonably have been expected to learn or discover

the serious health risks posed by use of the Recalled Devices prior to purchasing, leasing, recommending, paying for and/or reimbursing for, in whole or part, the Recalled Devices in general, and particularly given the representations, concealed material information, and omissions by Philips in its packaging, labels, advertising, websites, and other communications and disclosures; and (e) Philips has a duty to disclose information related to the health and safety of its products, including the Recalled Devices.

668. By concealing and failing to disclose the Defect, Philips intentionally, knowingly, and recklessly allowed its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures to mislead Plaintiffs, Class members, and their physicians, into believing that the Recalled Devices were safe for use.

669. Philips knew that its concealment and omissions regarding the Defect in its packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures were false, deceptive, inadequate, and misleading.

670. The information undisclosed and concealed by Philips was material. A reasonable consumer, including Plaintiffs and Class members, would find information that impacted on users' health and well-being, such as the serious adverse health risks associated with the use of the Recalled Devices, to be important when deciding whether to purchase, lease, pay for and/or reimburse payment for, in whole or part, the Recalled Devices.

671. As a result of such deceptive packaging, labels, advertisements, promotional materials, websites, and other communications and disclosures, Plaintiffs and the Class members justifiably and reasonably believed the Recalled Devices were safe for use.

672. Philips intentionally, knowingly, and recklessly concealed and omitted information about the Defect and its related serious health effects in its packaging, labels,

advertisements, promotional materials, websites, and other communications and disclosures regarding the Recalled Devices to induce Plaintiffs and Class members to purchase, lease, pay for, and/or reimburse for, in whole or part, the Recalled Devices.

673. Plaintiffs and Class members justifiably and reasonably relied on the omissions by Philips and purchased, leased, paid for, and/or reimbursed payment for, in whole or part, the Recalled Devices. Reasonable consumers would have been expected to rely on these omissions, in part, because they are omissions that seriously impact users' health and well-being.

674. Philips' fraudulent conduct actually and proximately caused harm to Plaintiffs and Class members because absent Philips' concealment and omissions, Plaintiffs and Class members would have behaved differently and would not have purchased, leased, paid for, and/or reimbursed payment for the Recalled Devices.

675. As a direct and proximate result of Philips' material omissions, misrepresentations, and concealment of material information regarding the Defect and its adverse health effects on users of the Recalled Devices, Plaintiffs and the Class members have suffered actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages.

**COUNT 9 – UNJUST ENRICHMENT (separately and in the alternative)**  
**On behalf of the Nationwide Class and all Subclasses**

676. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

677. This claim is brought against the Philips Defendants.

678. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

679. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

680. Philips was unjustly enriched as a result of its wrongful conduct.

681. Philips requested, received and appreciated a measurable direct financial benefit from the sale of its products to end consumers, including Plaintiffs and Class members, in the form of payment for and reimbursement payment for, in whole or part, the Recalled Devices.

682. Plaintiffs and Class members conferred a tangible and material economic benefit upon Philips by purchasing, leasing, paying for and/or reimbursing payment for, in whole or part, the Recalled Devices. Even when the sales or leases of Recalled Devices are made through intermediaries who then sell or lease to end users, the sales or leases of the Recalled Devices to

end users result in revenues which are either paid directly to Philips or used by the intermediaries to pay Philips for the Recalled Devices.

683. Plaintiffs and Class members would not have purchased, leased, paid for and/or reimbursed payment for, in whole or part, the Recalled Devices had they known about the Defect and the true risks of using the Recalled Devices.

684. Philips readily accepted and retained these benefits. Philips profited from the sales and leases of the Recalled Devices to the detriment and expense of Plaintiffs and Class members.

685. Philips appreciated these benefits which were the expected result of Philips acting in its pecuniary interest at the expense of its customers and users of the Recalled Devices. Philips knew it was acting to the detriment of Plaintiffs and Class members because Philips was aware of the Defect, Philips failed to disclose this knowledge, and thereby misled Plaintiffs and Class members regarding the nature and quality of the Recalled Devices while profiting from this deception.

686. There is no justification for Philips' enrichment. Under these circumstances, it would be unjust, inequitable, and unconscionable for Philips to retain the economic benefits it received at the expense of Plaintiffs and the Class because they were procured as a result of Philips' wrongful conduct. Failing to require Philips to provide remuneration under these circumstances would result in Philips being unjustly enriched at the expense of Plaintiffs and Class members who endure being exposed to the risk of developing serious medical conditions and can no longer use their machines safely.

687. Philips' retention of the benefits conferred upon it by Plaintiffs and the Class would be unjust and inequitable.



688. Plaintiffs are entitled to restitution of the benefits Philips unjustly retained and/or any amounts necessary to return Plaintiffs to the position they occupied prior to dealing with Philips, such amounts to be determined at trial.

689. Plaintiffs plead this claim separately as well as in the alternative to their other claims, as without such claims they would have no adequate legal remedy.

690. Plaintiffs and the Class suffered damages in an amount to be determined at trial.

**COUNT 10 – VIOLATIONS OF ALABAMA DECEPTIVE TRADE PRACTICES ACT**

**Ala. Code § 8-19-1, et seq.**

**On Behalf of the Alabama Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

691. Plaintiffs Goodenough, Brengle, Byrge and De Journette (“Alabama Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

692. Alabama Plaintiffs bring this cause of action individually and on behalf of the members of the Alabama Subclass.

693. This claim is brought against the Philips Defendants.

694. The Alabama Deceptive Trade Practices Act (“ADTPA”) was created to protect Alabama consumers from fraudulent or deceptive business practices.

695. Philips is a “person,” and Alabama Plaintiffs and Alabama Subclass members are “consumers” under the ADTPA.

696. Alabama Plaintiffs and Alabama Subclass members are consumers who purchased, leased, or reimbursed payment for the Recalled Devices for personal use.

697. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Alabama. In addition, Philips, among other things, sold the Recalled Devices in Alabama, shipped Recalled Devices to Alabama, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Alabama.

698. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

699. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

700. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) advertising goods with intent not to sell as advertised; (d) engaging in fraudulent, deceptive, unconscionable, and unfair conduct that creates a likelihood of confusion and misunderstanding; and (e) engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

701. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Alabama Plaintiffs. Ordinary consumers, including Alabama Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Alabama Plaintiffs', as well as Alabama Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

702. Philips owed Alabama Plaintiffs and Alabama Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Alabama Plaintiffs or Alabama Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

703. Alabama Plaintiffs and members of the Alabama Subclass justifiably relied on the material representations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

704. Philips' conduct actually and proximately caused an actual ascertainable loss of money or property to Alabama Plaintiffs (as set forth above) and members of the Alabama Subclass. Absent Philips' unfair, deceptive, fraudulent and/or unconscionable conduct, Alabama Plaintiffs and Alabama Subclass members would have behaved differently and would not have

purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Alabama Plaintiffs and Alabama Subclass members to purchase, lease, or reimburse payment for Recalled Devices, which they would not otherwise have done. Alabama Plaintiffs and Alabama Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

705. Accordingly, pursuant to Ala. Code § 8-19-10(a)(1), Alabama Plaintiffs and Alabama Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Alabama Plaintiffs and Alabama Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

706. To the extent that any pre-suit notice was purportedly required, Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Additional notice letters were served on Philips before this

MDL was formed and months before the filing of any Consolidated Class Action Complaint for Economic Losses by plaintiffs who brought putative class actions that have been consolidated in this MDL. These letters put Philips on notice of the demands of the Alabama Plaintiffs and Alabama Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Alabama Plaintiffs and Alabama Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, Plaintiffs are not required to provide pre-suit notice because Philips does not maintain a place of business or does not keep assets within the state of Alabama. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 11 – VIOLATIONS OF ALASKA UNFAIR TRADE PRACTICES AND  
CONSUMER PROTECTION ACT**

*Alaska Stat. § 45.50.471, et seq.*

**On Behalf of the Alaska Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

707. Plaintiffs ASEA Health Trust and Ohio Carpenters ("Alaska Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

708. Alaska Plaintiffs bring this cause of action individually and on behalf of the members of the Alaska Subclass.

709. This claim is brought against the Philips Defendants.

710. The Alaska Unfair Trade Practices and Consumer Protection Act was created to protect Alaska consumers from deceptive and unfair business practices.

711. Alaska Plaintiffs and Alaska Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

712. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Alaska. In addition, Philips, among other things, sold the Recalled Devices in Alaska, shipped Recalled Devices to Alaska, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Alaska.

713. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

714. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

715. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of trade or commerce and thus is unlawful under Alaska Stat. § 45.50.471, *et seq.*

716. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable, and unfair business practices: (a) misrepresenting that the

Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

717. Philips' conduct was fraudulent, deceptive, and unconscionable because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Alaska Plaintiffs. Ordinary consumers, including Alaska Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Alaska Plaintiffs', as well as other Alaska Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

718. Philips owed Alaska Plaintiffs and Alaska Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Alaska Plaintiffs or Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

719. Alaska Plaintiffs, and members of the Alaska Subclass, justifiably relied on the material representations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

720. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Alaska Plaintiffs (as set forth above) and members of the Alaska Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Alaska Plaintiffs and Alaska Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Alaska Plaintiffs and Alaska Subclass members to purchase, lease, or reimburse payment for Recalled Devices, which they would not otherwise have done. Alaska Plaintiffs and Alaska Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

721. Accordingly, pursuant to Alaska Stat. § 45.50.531(a), Alaska Plaintiffs and Alaska Subclass members are entitled to recover either: (1) three times their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages; or (2) \$500; whichever is greater. In addition, Alaska Plaintiffs and Alaska Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

722. To the extent that any pre-suit notice was purportedly required, Alaska Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a



year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. These letters put Philips on notice of the demands of the Alaska Plaintiffs and Alaska Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Alaska Plaintiffs and Alaska Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of Alaska. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 12 – VIOLATIONS OF ARIZONA CONSUMER FRAUD ACT**

**Ariz. Rev. Stat. § 44-1521, *et seq.***

**On Behalf of the Arizona Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

723. Plaintiffs Gilliard-Gunter, Groudan, and Ohio Carpenters (“Arizona Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

724. Arizona Plaintiffs bring this cause of action individually and on behalf of the members of the Arizona Subclass.

725. This claim is brought against the Philips Defendants.

726. The Arizona Consumer Fraud Act was created to protect Arizona consumers from deceptive and unfair business practices.

727. Arizona Plaintiffs and Arizona Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

728. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Arizona. In addition, Philips, among other things, sold the

Recalled Devices in Arizona, shipped Recalled Devices to Arizona, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Arizona.

729. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

730. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

731. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Arizona, making it unlawful under Ariz. Rev. Stat. § 44-1521, *et seq.*

732. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and misleading business practices: (a) misrepresenting that the Recalled

Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

733. Philips' conduct was fraudulent, deceptive, and misleading because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Arizona Plaintiffs. Ordinary consumers, including Arizona Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Arizona Plaintiffs', as well as other Arizona Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

734. Philips owed Arizona Plaintiffs and Arizona Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Arizona Plaintiffs or Arizona Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

735. Arizona Plaintiffs and members of the Arizona Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

736. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Arizona Plaintiffs (as set forth above) and members of the Arizona Subclass. Absent Philips' misleading, deceptive and/or fraudulent conduct, Arizona Plaintiffs and Arizona Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Arizona Plaintiffs and Arizona Subclass members to purchase, lease, or reimburse payment for Recalled Devices, which they would not otherwise have done. Arizona Plaintiffs and Arizona Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

737. Accordingly, pursuant to Ariz. Rev. Stat. § 44-1528(A), Arizona Plaintiffs and Arizona Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Arizona Plaintiffs and Arizona Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 13 – VIOLATIONS OF ARKANSAS DECEPTIVE TRADE PRACTICES ACT**

**Ark. Code. § 4-88-101, *et seq.***

**On Behalf of the Arkansas Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

738. Plaintiff Autry (“Arkansas Plaintiff”) realleges and incorporates by reference all preceding allegations as though fully set forth herein.

739. Arkansas Plaintiff brings this cause of action individually and on behalf of the members of the Arkansas Subclass.

740. This claim is brought against the Philips Defendants.

741. The Arkansas Deceptive Trade Practices Act was created to protect Arizona consumers from deceptive and unfair business practices.

742. Arkansas Plaintiff and Arkansas Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

743. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Arkansas. In addition, Philips, among other things, sold the Recalled Devices in Arkansas, shipped Recalled Devices to Arkansas, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Arkansas.

744. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

745. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

746. Philips' conduct constituted, among other things, the following prohibited deceptive and unconscionable business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) advertising goods with intent not to sell as advertised; and (d) engaging in deceptive and unconscionable conduct that creates a likelihood of confusion and misunderstanding.

747. Philips' conduct was fraudulent, deceptive, misleading, and unconscionable because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Arkansas Plaintiff. Ordinary consumers, including Arkansas Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Arkansas Plaintiff's, as well as other Arkansas Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

748. Philips owed Arkansas Plaintiff and Arkansas Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Arkansas Plaintiff or Arkansas Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

749. Arkansas Plaintiff and members of the Arkansas Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

750. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Arkansas Plaintiff (as set forth above) and members of the Arkansas Subclass. Absent Philips' misleading, deceptive and/or fraudulent conduct, Arkansas Plaintiff and Arkansas Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Arkansas Plaintiff and Arkansas Subclass members to purchase, lease, or reimburse payment for Recalled Devices, which they would not otherwise have done. Arkansas Plaintiffs and Arkansas Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

751. Accordingly, pursuant to Ark. Code § 4-88-113(f)(1), Arkansas Plaintiff and Arkansas Subclass members are entitled to recover their actual damages, which can be calculated

with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Arkansas Plaintiff and Arkansas Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 14 – VIOLATIONS OF CALIFORNIA UNFAIR COMPETITION LAW**  
**Cal. Bus. & Prof. Code § 17200, *et seq.* (Unfair and Fraudulent Prongs)**  
**On Behalf of the California Subclass, except for Class Members**  
**who purchased or leased a Recalled Device for business use only**

752. Plaintiffs Bailey, Bastasch, Campbell, Krantz, Luenebrink, Mest, Mitrovich, Nielson, Ruiz, Waybright, and MSP ("California Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

753. California Plaintiffs bring this cause of action individually and on behalf of the members of the California Subclass.

754. This claim is brought against the Philips Defendants.

755. California Unfair Competition Law ("UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

756. Philips is a "person" under the UCL.

757. California Plaintiffs and California Subclass members are consumers who purchased, leased, or reimbursed payment for the Recalled Products for personal purposes.



758. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in California. In addition, Philips, among other things, sold the Recalled Devices in California, shipped Recalled Devices to California, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in California.

759. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

760. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

761. Philips conduct constitutes "unfair" business acts and practices under the UCL in that Philips' conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Philips' conduct outweighs any conceivable benefit of such conduct.

762. Philips has, in the course of its business and in the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by, among other things, concealing the true risks of the Recalled Devices.

763. The above-described unfair business acts or practices presented a threat and likelihood of harm and deception to California Plaintiffs and California Subclass members in that Philips systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

764. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

765. Philips' conduct was fraudulent, deceptive, and unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers and the general public, including California Plaintiffs. Ordinary consumers, including California Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in California Plaintiffs', as well as other California Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

766. Philips owed California Plaintiffs and California Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not California Plaintiffs or California Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

767. California Plaintiffs and members of the California Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being. California Plaintiffs and California Subclass members are reasonable consumers who did not expect the risks that resulted from using the Recalled Devices.

768. Philips' conduct in concealing and failing to disclose the true risks of the Recalled Devices was unfair in violation of the UCL because, among other things, it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

769. The gravity of harm resulting from Philips' unfair conduct outweighs any potential utility. The practice of selling Recalled Devices that present a substantial health risk to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

770. The harm from Philips' conduct was not reasonably avoidable by consumers because only Philips was aware of the true facts concerning the risks of its Recalled Devices, and Philips did not disclose them, despite knowing of such defects. California Plaintiffs and

California Subclass members did not know of and had no reasonable means of discovering the true risk of using the Recalled Devices.

771. California Plaintiffs and California Subclass members suffered injury in fact and have lost money as a result of Philips' fraudulent business acts or practices and Philips' unfair conduct. In turn, through their unfair conduct, Philips acquired money that California Plaintiffs and California Subclass members previously owned.

772. Philips' conduct actually and proximately caused an ascertainable loss of money or property to California Plaintiffs (as set forth above) and members of the California Subclass. Absent Philips' misleading, deceptive and/or fraudulent conduct, California Plaintiffs and California Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced California Plaintiffs and California Subclass members to purchase, lease, or reimburse payment for Recalled Devices they would not otherwise have purchased, leased, or reimbursed payment for. California Plaintiffs and California Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

773. Accordingly, pursuant to the Cal. Bus. & Prof. Code § 17200, *et seq.*, California Plaintiffs and California Subclass members are entitled to restitution, injunctive and other injunctive relief, and reasonable attorneys' fees, as well as any other relief the Court may deem just or proper.

**COUNT 15 – VIOLATIONS OF CALIFORNIA UNFAIR COMPETITION LAW**

**Cal. Bus. & Prof. Code § 17200, *et seq.* (Unlawful Prong)  
On Behalf of the California Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

774. Plaintiffs Bailey, Bastasch, Campbell, Krantz, Luenebrink, Mest, Mitrovich, Nielson, Ruiz, Waybright, and MSP (“California Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

775. California Plaintiffs bring this cause of action individually and on behalf of the members of the California Subclass.

776. This claim is brought against the Philips Defendants.

777. Philips are “persons” under the California Unfair Competition Law (“UCL”).

778. California Plaintiffs and California Subclass members are “consumers” who purchased, leased, or reimbursed payment for the Recalled Products for personal purposes under the UCL.

779. The UCL prohibits any “unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising.” By engaging in business practices which are also unlawful, Philips have violated the UCL.

780. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in California. In addition, Philips, among other things, sold the Recalled Devices in California, shipped Recalled Devices to California, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in California.

781. Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines

due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

782. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

783. As set forth in detail throughout this Complaint, Philips' conduct constituted "unlawful" acts and practices which include RICO violations, breach of express warranty, breach of implied warranties, violations of the Magnuson-Moss Federal Warranty Act, common law fraud, negligent failure to recall or conducting a negligent recall, violations of state (including California's) consumer protection statutes, and unjust enrichment.

784. California Plaintiffs and California Subclass members conferred tangible and material economic benefits upon Philips by purchasing, leasing, or reimbursing payment for the Recalled Devices. California Plaintiffs and California Subclass members would not have purchased, leased, or reimbursed payment for the Recalled Devices had they known of the Defect and the associated serious health risks.

785. Philips reaped unjust profits, revenue, and benefits by virtue of their UCL violations.

786. Accordingly, pursuant to the Cal. Bus. & Prof. Code § 17200, *et seq.*, California Plaintiffs and California Subclass members seek restitutionary disgorgement of these unjust profits and revenues along with injunctive relief and reasonable attorneys’ fees, as well as any other relief the Court may deem just or proper.

**COUNT 16 – VIOLATIONS OF CALIFORNIA CONSUMERS LEGAL REMEDIES ACT**

**Cal. Civ. Code § 1750, *et seq.***

**On Behalf of the California Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

787. Plaintiffs Bailey, Bastasch, Campbell, Krantz, Luenebrink, Mest, Mitrovich, Nielson, Ruiz, Waybright, and MSP (“California Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

788. California Plaintiffs bring this cause of action individually and on behalf of the members of the California Subclass.

789. This claim is brought against the Philips Defendants.

790. The California Consumers Legal Remedies Act (“CLRA”) protects California consumers from deceptive and unfair trade practices.

791. Philips are “persons” under the CLRA.

792. California Plaintiffs and California Subclass members are “consumers” who purchased, leased, or reimbursed payment for the Recalled Products for personal purposes under the CLRA.

793. The Recalled Devices are “goods” under the CLRA.

794. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in California. In addition, Philips, among other things, sold the Recalled Devices in California, shipped Recalled Devices to California, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in California.

795. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

796. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

797. Philips' conduct described herein constitutes the knowing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in California, and was made by Philips with knowledge of the serious health risks associated with use of the Recalled Devices and with the intention that California Plaintiffs and California Subclass members would rely on such conduct in purchasing the Recalled Devices, making it unlawful under Cal. Civ. Code § 1750, *et seq.*

798. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled



Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

799. Philips' conduct was fraudulent, deceptive, and unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including California Plaintiffs. Ordinary consumers, including California Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in California Plaintiffs', as well as other California Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

800. Philips owed California Plaintiffs and California Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not California Plaintiffs or California Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

801. California Plaintiffs and members of the California Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these misrepresentations and/or omissions, in part, because they

are misrepresentations and/or omissions that impact seriously on a consumer's health and well-being.

802. Philips' conduct actually and proximately caused an ascertainable loss of money or property to California Plaintiffs (as set forth above) and members of the California Subclass. Absent Philips' unfair, deceptive, fraudulent and/or unconscionable conduct, California Plaintiffs and California Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for Recalled Devices. Philips' omissions induced California Plaintiff and California Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. California Plaintiffs and California Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

803. Accordingly, pursuant to the Cal. Civ. Code § 1750, *et seq.*, California Plaintiffs and California Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, California Plaintiffs and California members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

804. To the extent that any pre-suit notice was purportedly required, California Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Additional notice letters were served on Philips before this MDL was formed and months before the filing of any Consolidated Class Action Complaint for Economic Losses by plaintiffs who brought putative class actions that have been consolidated in this MDL. These letters put Philips on notice of the demands of the California Plaintiffs and California Subclass, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate California Plaintiffs and California Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 17 – VIOLATIONS OF CALIFORNIA FALSE ADVERTISING LAW**

**Cal. Bus. & Prof. Code § 17500, *et seq.***

**On Behalf of the California Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

805. Plaintiffs Bailey, Bastasch, Campbell, Krantz, Luenebrink, Mest, Mitrovich, Nielson, Ruiz, Waybright, and MSP ("California Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

806. California Plaintiffs bring this cause of action individually and on behalf of the members of the California Subclass.

807. This claim is brought against the Philips Defendants.

808. The California False Advertising Law was created to protect California consumers from deceptive, misleading, and false advertising practices.

809. California Plaintiffs and California Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

810. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in California. In addition, Philips, among other things, sold the Recalled Devices in California, shipped Recalled Devices to California, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in California.

811. As set forth more fully above, Philips marketed, advertised, and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into the users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

812. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

813. Philips' conduct described herein constitutes the knowing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in California, making it unlawful under Cal. Bus. & Prof. Code § 17500, *et seq.*

814. Philips' conduct was fraudulent, deceptive, and unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including California Plaintiffs. Ordinary consumers, including California Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in California Plaintiffs', as well as other California Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

815. Philips owed California Plaintiffs and California Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not California Plaintiffs or Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

816. California Plaintiffs and members of the California Subclass justifiably relied on the material representations and/or omissions by Philips, and reasonable consumers would have

been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

817. Philips' conduct actually and proximately caused an ascertainable loss of money or property to California Plaintiffs (as set forth above) and members of the California Subclass. Absent Philips' unfair, deceptive, fraudulent and/or unconscionable conduct, California Plaintiffs and California Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes. Philips' omissions induced California Plaintiffs and California Subclass members to purchase, lease, or reimburse payment for the Recalled Devices they would not otherwise have purchased, leased, or reimbursed payment for. California Plaintiffs and California Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

818. Accordingly, pursuant to Cal. Bus. & Prof. Code § 17500, *et seq.*, California Plaintiffs and California Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, California Plaintiffs and California Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 18 – VIOLATIONS OF COLORADO CONSUMER PROTECTION ACT**

**Colo. Rev. Stat. § 6-1-101, *et seq.***

**On Behalf of the Colorado Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

819. Plaintiffs Archuleta and McDaniel (“Colorado Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

820. Colorado Plaintiffs bring this cause of action individually and on behalf of the members of the Colorado Subclass.

821. This claim is brought against the Philips Defendants.

822. The Colorado Consumer Protection Act was created to protect Colorado consumers from deceptive, unconscionable, deliberately misleading, false fraudulent and/or unfair business practices.

823. Colorado Plaintiffs and Colorado Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

824. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Colorado. In addition, Philips, among other things, sold the Recalled Devices in Colorado, shipped Recalled Devices to Colorado, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Colorado.

825. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health

professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

826. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

827. Philips' conduct described herein constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Colorado, and was made with the intention that Colorado Plaintiffs and Colorado Subclass members would rely upon such conduct in purchasing the Recalled Devices, significantly impacting consumers and making it unlawful under Colo. Rev. Stat. § 6-1-101, *et seq.*

828. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unfair and/or unconscionable business practices: (a) knowingly or recklessly misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) advertising goods or services with intent not to sell them as advertised; (d) failing to disclose material information concerning goods or services which was known at the time of an advertisement or sale and intended to induce a consumer to enter into a transaction; and (e)



knowingly or recklessly engaging in other unfair, unconscionable, deceptive, deliberately misleading, false, or fraudulent act or practices.

829. Philips' conduct was fraudulent and deceptive because the misrepresentations and omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Colorado Plaintiffs. Reasonable consumers, including Colorado Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Colorado Plaintiffs', as well as Colorado Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

830. Philips owed Colorado Plaintiffs and Colorado Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Colorado Plaintiffs or Colorado Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

831. Colorado Plaintiffs and members of the Colorado Subclass justifiably relied on the misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these misrepresentations and/or omissions, in part, because they are misrepresentations and/or omissions that impact seriously on a consumer's health and well-being.

832. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Colorado Plaintiffs (as set forth above) and members of the Colorado Subclass. Absent Defendants' unfair, deceptive, fraudulent and/or unconscionable conduct, Colorado Plaintiffs and Colorado Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes. Philips' omissions induced Colorado Plaintiffs and Colorado Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

833. Accordingly, pursuant to Colo. Rev. Stat. § 6-1-101, *et seq.*, Colorado Plaintiffs and Colorado Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Colorado Plaintiffs and Colorado Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 19 – VIOLATIONS OF CONNECTICUT UNFAIR TRADE PRACTICES ACT**

**Conn. Gen. Stat. §§ 42-110a-110q, *et seq.***

**On Behalf of the Connecticut Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

834. Plaintiffs Gottlieb, Rohan, Toscano, and MSP ("Connecticut Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

835. Connecticut Plaintiffs bring this cause of action individually and on behalf of the members of the Connecticut Subclass.

836. This claim is brought against the Philips Defendants.

837. The Connecticut Unfair Trade Practices Act (“CUPTA”) was created to protect Connecticut consumers from fraudulent or deceptive business practices.

838. Philips is a “person” as defined by CUPTA.

839. Connecticut Plaintiffs and Connecticut Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

840. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Connecticut. In addition, Philips, among other things, sold the Recalled Devices in Connecticut, shipped Recalled Devices to Connecticut, and otherwise engaged in trade or commerce, or conducted, business related to the Recalled Devices in Connecticut.

841. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

842. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were

defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

843. Philips' conduct described herein constitutes the knowing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Connecticut, making it unlawful under Conn. Gen. Stat. § 42-110a, *et seq.*

844. Philips' conduct was fraudulent and deceptive because the misrepresentations and omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Connecticut Plaintiffs. Reasonable consumers, including Connecticut Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Connecticut Plaintiffs', as well as Connecticut Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices for personal purposes.

845. Philips owed Connecticut Plaintiffs and Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Connecticut Plaintiffs or Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips

intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

846. Connecticut Plaintiffs and members of the Connecticut Subclass justifiably relied on the material representations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions.

847. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Connecticut Plaintiffs (as set forth above) and members of the Connecticut Subclass. Absent Defendants' unfair and fraudulent conduct, Connecticut Plaintiffs and Connecticut Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Connecticut Plaintiffs and Connecticut Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

848. Accordingly, pursuant to Conn. Gen. Stat. § 42-110a, *et seq.*, Connecticut Plaintiffs and Connecticut Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Connecticut Plaintiffs and Connecticut Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 20 – VIOLATIONS OF DELAWARE CONSUMER FRAUD ACT**

**Del. Code Ann. tit. 6, § 2511, *et seq.***

**On Behalf of the Delaware Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

849. Plaintiffs George and Gibbons (“Delaware Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

850. Delaware Plaintiffs bring this cause of action individually and on behalf of the members of the Delaware Subclass.

851. This claim is brought against the Philips Defendants.

852. The Delaware Consumer Fraud Act (“DCFA”) was created to protect Delaware consumers from deceptive and unfair business practices.

853. Philips is a “person,” and the Recalled Devices are “merchandise” as defined by the DCFA.

854. Delaware Plaintiffs purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

855. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Delaware. In addition, Philips, among other things, sold the Recalled Devices in Delaware, shipped Recalled Devices to Delaware, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Delaware.

856. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed significant risks of substantial physical injury to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users,

payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

857. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

858. Philips' conduct described herein constitutes the act, use or employment of conduct in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Delaware, which conduct created confusion or misunderstanding on the part of Delaware Plaintiffs and Delaware Subclass members, making it unlawful under Del. Code Ann. tit. 6, § 2511, *et seq.*

859. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

860. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Delaware Plaintiffs. Reasonable consumers, including Delaware Plaintiffs, would have found it material to their purchasing

decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Delaware Plaintiffs', as well as Delaware Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices for personal purposes.

861. Philips owed Delaware Plaintiffs and Delaware Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Delaware Plaintiffs or Delaware Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

862. Delaware Plaintiffs and members of the Delaware Subclass reasonably and justifiably relied on the material representations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions.

863. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Delaware Plaintiffs (as set forth above) and members of the Delaware Subclass. Absent Defendants' unfair and fraudulent conduct, Delaware Plaintiffs and Delaware Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Delaware Plaintiffs and Delaware Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.



864. Accordingly, pursuant to Del. Code Ann. tit. 6, § 2511, *et seq.*, Delaware Plaintiffs and Delaware Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Delaware Plaintiffs and Delaware Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 21 – VIOLATIONS OF DISTRICT OF COLUMBIA CONSUMER  
PROTECTION PROCEDURES ACT**

**D.C. Code § 28-3901, *et seq.***

**On Behalf of the D.C. Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

865. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

866. Plaintiffs bring this cause of action individually and on behalf of the members of the D.C. Subclass.

867. This claim is brought against the Philips Defendants.

868. The District of Columbia Consumer Protection Procedures Act ("CPPA") was created to protect District of Columbia ("D.C.") consumers from deceptive and unfair business practices.

869. Philips is a merchant under the CPPA and furnishes, makes available, provides information about, or, directly or indirectly, solicits or offers for or effectuates, a sale, lease or transfer of consumer goods or services.

870. Plaintiffs and D.C. Subclass members are consumers who purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

871. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in D.C. In addition, Philips, among other things, sold the Recalled Devices in D.C., shipped Recalled Devices to D.C., and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in D.C.

872. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed significant risks of substantial physical injury to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

873. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

874. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) advertising or offering goods or services with intent not to sell them as advertised or offered; (d) misrepresenting a material fact which has a tendency to mislead; (e) failing to state a material fact when such failure tends to mislead; and (f) representing that the subject of a transaction has been supplied in accordance with a previous representation when it has not.

875. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to mislead and, in fact, did mislead, reasonable consumers, including Plaintiffs. Reasonable consumers, including Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in D.C. Plaintiffs', as well as D.C. Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices for personal purposes.

876. Philips owed D.C. Plaintiffs and D.C. Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not D.C. Plaintiffs or D.C. Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for

consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

877. D.C. Plaintiffs and members of the D.C. Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

878. Philips' conduct actually and proximately caused an ascertainable loss of money or property to D.C. Plaintiffs (as set forth above) and members of the D.C. Subclass. Absent Defendants' unfair, deceptive and fraudulent conduct, D.C. Plaintiffs and D.C. Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced D.C. Plaintiffs and D.C. Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

879. Accordingly, pursuant to D.C. Code § 28-3901, *et seq.*, D.C. Plaintiffs and D.C. Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, D.C. Plaintiffs and D.C. Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 22 – VIOLATIONS OF FLORIDA DECEPTIVE AND UNFAIR TRADE  
PRACTICES ACT**

**Fla. Stat. Ann. § 501.201, *et seq.***

**On Behalf of the Florida Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

880. Plaintiffs Boyd, Dzierzanowski, Fields, Morris, Paraday, Smith, Ward, Ohio Carpenters, and MSP (“Florida Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

881. Florida Plaintiffs bring this cause of action individually and on behalf of the members of the Florida Subclass.

882. This claim is brought against the Philips Defendants.

883. The Florida Deceptive and Unfair Trade Practices and Act was created to protect Florida consumers from unfair methods of competition and deceptive, unconscionable, unfair business practices.

884. Florida Plaintiffs and Florida Subclass members are individuals who purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

885. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Florida. In addition, Philips, among other things, sold the Recalled Devices in Florida, shipped Recalled Devices to Florida, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Florida.

886. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips

intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

887. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

888. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) were immoral, unethical, oppressive, outrageous, unscrupulous, and substantially injurious; and caused substantial harm that greatly outweighs any possible utility from the conduct.

889. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Florida Plaintiffs. Reasonable consumers, including Florida Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Florida Plaintiffs', as well as

Florida Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices for personal purposes.

890. Philips owed Florida Plaintiffs and Florida Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Florida Plaintiffs or Florida Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

891. Florida Plaintiffs and members of the Florida Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

892. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Florida Plaintiffs (as set forth above) and members of the Florida Subclass. Absent Defendants' unfair and fraudulent conduct, Florida Plaintiffs and Florida Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Florida Plaintiffs and Florida Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

893. Accordingly, pursuant to the aforementioned statutes, Florida Plaintiffs and Florida Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those

damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Florida Plaintiffs and Florida Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 23 – VIOLATIONS OF FLORIDA FALSE ADVERTISING STATUTE**

**Fla. Stat. Ann. §§ 817.06, 817.41, *et seq.***

**On Behalf of the Florida Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

894. Plaintiffs Boyd, Dzierzanowski, Fields, Morris, Paraday, Smith, Ward, Ohio Carpenters, and MSP ("Florida Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

895. Florida Plaintiffs bring this cause of action individually and on behalf of the members of the Florida Subclass.

896. This claim is brought against the Philips Defendants.

897. The Florida False Advertising Statute was created to protect Florida consumers from deceptive and unfair advertising practices.

898. Florida Plaintiffs and Florida Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

899. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Florida. In addition, Philips, among other things, sold the Recalled Devices in Florida, shipped Recalled Devices to Florida, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Florida.



900. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed significant risks of substantial physical injury to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

901. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

902. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement of merchandise, the Recalled Devices, in trade or commerce in Florida and was made with the intention that Florida Plaintiffs and Florida Subclass members rely on such advertisements in purchasing the Recalled Devices, making it unlawful under Fla. Stat. Ann. § 817.06 and § 817.41, *et seq.*

903. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Florida Plaintiffs. Reasonable consumers, including Florida Plaintiffs, would have found it

material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Florida Plaintiffs', as well as Florida Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices for personal purposes.

904. Philips owed Florida Plaintiffs and Florida Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Florida Plaintiffs or Florida Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

905. Florida Plaintiffs and members of the Florida Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions.

906. Philips' conduct actually and proximately caused actual damages to Florida Plaintiffs (as set forth above) and members of the Subclass. Absent Defendants' unfair and fraudulent conduct, Florida Plaintiffs and Florida Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Florida Plaintiffs and Florida Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

907. Accordingly, under Fla. Stat. Ann. § 817.06 and § 817.41, *et seq.*, Florida Plaintiffs and Florida Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Florida Plaintiffs and Florida Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 24 – VIOLATIONS OF GEORGIA UNIFORM DECEPTIVE TRADE PRACTICES ACT**

**Ga. Code. Ann. § 10-1-370, *et seq.***

**On Behalf of the Georgia Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

908. Plaintiffs Childre, Davis, Fultz, Lewis, Luke, Mercure, and Sizemore ("Georgia Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

909. Georgia Plaintiffs bring this cause of action individually and on behalf of the members of the Georgia Subclass.

910. This claim is brought against the Philips Defendants.

911. The Georgia Uniform Deceptive Trade Practices Act was created to protect Georgia consumers from deceptive and unfair business practices.

912. Georgia Plaintiffs and Georgia Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

913. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Georgia. In addition, Philips, among other things, sold the Recalled Devices in Georgia, shipped Recalled Devices to Georgia, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Georgia.

914. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed significant risks of substantial physical injury to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

915. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

916. Philips' conduct constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Georgia, making it unlawful under Ga. Code. Ann. § 10-1-370, *et seq.*

917. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, benefits or quantities, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) advertising the Recalled Devices with intent not to sell them as advertised; and (d) engaging in other conduct that creates a likelihood of confusion or of misunderstanding.

918. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Georgia Plaintiffs. Reasonable consumers, including Georgia Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Georgia Plaintiffs', as well as other Georgia Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

919. Philips owed Georgia Plaintiffs and Georgia Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Georgia Plaintiffs or Georgia Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

920. Georgia Plaintiffs and members of the Georgia Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

921. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Georgia Plaintiffs (as set forth above) and members of the Georgia Subclass, who are also likely to be damaged in the future on an ongoing basis in the future. Absent Philips' unfair and fraudulent conduct, Georgia Plaintiffs and Georgia Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Georgia Plaintiffs and Georgia Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

922. Accordingly, pursuant to Ga. Code. Ann. § 10-1-370, *et seq.*, Georgia Plaintiffs and Georgia Subclass members are entitled to injunctive relief, reasonable attorneys' fees, as well as equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 25 – VIOLATIONS OF GEORGIA FAIR BUSINESS PRACTICES ACT**

**Ga. Code. Ann. § 10-1-390, *et seq.***

**On Behalf of the Georgia Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

923. Plaintiffs Childre, Davis, Fultz, Lewis, Luke, Mercure, and Sizemore ("Georgia Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

924. Georgia Plaintiffs bring this cause of action individually and on behalf of the members of the Georgia Subclass.

925. This claim is brought against the Philips Defendants.

926. The Georgia Fair Business Practices Act was created to protect Georgia consumers from deceptive and unfair business practices.

927. Georgia Plaintiffs and Georgia Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

928. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Georgia. In addition, Philips, among other things, sold the Recalled Devices in Georgia, shipped Recalled Devices to Georgia, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Georgia.

929. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

930. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

931. Philips' conduct constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Georgia, making it unlawful under Ga. Code. Ann. § 10-1-390, *et seq.*

932. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices have a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) advertising goods with intent not to sell them as advertised.

933. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Georgia Plaintiffs. Reasonable consumers, including Georgia Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious bodily injury and other health consequences. Knowledge of those facts would have been a substantial factor in Georgia Plaintiffs', as well as Georgia Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

934. Philips owed Georgia Plaintiffs and Georgia Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Georgia Plaintiffs or Georgia Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because



Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

935. Georgia Plaintiffs and members of the Georgia Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

936. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Georgia Plaintiffs (as set forth above) and members of the Georgia Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Georgia Plaintiffs and Georgia Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Georgia Plaintiffs and Georgia Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

937. Accordingly, pursuant Ga. Code. Ann. § 10-1-390, *et seq.*, Georgia Plaintiffs and Georgia Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Georgia Plaintiffs and Georgia Subclass members are entitled to injunctive relief and all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

938. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for over a year. Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Additional notice letters were served on Philips before this MDL was formed and months before the filing of any Consolidated Class Action Complaint for Economic Losses by plaintiffs who brought putative class actions that have been consolidated in this MDL. These letters put Philips on notice of the demands of the Georgia Plaintiffs and Georgia Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Georgia Plaintiffs and Georgia Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, Plaintiffs are not required to provide pre-suit notice because Philips does not maintain a place of business or does not keep assets within the state of Georgia. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 26 – VIOLATIONS OF HAWAII UNFAIR AND DECEPTIVE ACTS OR PRACTICES ACT**

**Haw. Rev. Stat. § 480-1, *et seq.***

**On Behalf of the Hawaii Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

939. Plaintiff Brown ("Hawaii Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

940. Hawaii Plaintiff brings this cause of action individually and on behalf of the members of the Hawaii Subclass.

941. This claim is brought against the Philips Defendants.

942. The Hawaii Unfair and Deceptive Acts or practices Act was created to protect Hawaii consumers from deceptive and unfair business practices.

943. Hawaii Plaintiff and Hawaii Subclass members are consumers who purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

944. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Hawaii. In addition, Philips, among other things, sold the Recalled Devices in Hawaii, shipped Recalled Devices to Hawaii, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Hawaii.

945. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

946. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

947. Philips' conduct constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Hawaii, making it unlawful under Haw. Rev. Stat. § 480-1, *et seq.*

948. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Hawaii Plaintiff. Reasonable consumers, including Hawaii Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Hawaii Plaintiff's, as well as Hawaii Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

949. Philips owed Hawaii Plaintiff and Hawaii Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Hawaii Plaintiff or Hawaii Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

950. Hawaii Plaintiff and members of the Hawaii Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

951. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Hawaii Plaintiff (as set forth above) and members of the Hawaii Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Hawaii Plaintiff and Hawaii Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Hawaii Plaintiff and Hawaii Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

952. Accordingly, pursuant Haw. Rev. Stat. § 480-1, *et seq.*, Hawaii Plaintiff and Hawaii Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Hawaii Plaintiff and Hawaii Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 27 – VIOLATIONS OF HAWAII UNIFORM DECEPTIVE TRADE PRACTICE**  
**VIOLATIONS**

**HAW. REV. STAT. § 481A-1, *et seq.***

**On Behalf of the Hawaii Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

953. Plaintiff Brown ("Hawaii Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

954. Hawaii Plaintiff brings this action individually and on behalf of the members of the Hawaii Subclass.

955. This claim is brought against the Philips Defendants.

956. The Hawaii Uniform Deceptive Trade Practice Act was created to protect Hawaii consumers from deceptive and unfair business practices.

957. Hawaii Plaintiff and Hawaii Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

958. Philips is a “person” as defined in Haw. Rev. Stat. § 481A-2.

959. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Hawaii. In addition, Philips, among other things, sold the Recalled Devices in Hawaii, shipped Recalled Devices to Hawaii, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Hawaii.

960. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

961. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of

the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

962. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices have a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) advertising goods with intent not to sell them as advertised; and (d) engaging in other conduct which similarly creates a likelihood of confusion or of misunderstanding.

963. Philips' conduct was fraudulent and deceptive because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including Hawaii Plaintiff. Reasonable consumers, including Hawaii Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious bodily injury and other health consequences. Knowledge of those facts would have been a substantial factor in Hawaii Plaintiff's, as well as Hawaii Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

964. Philips owed Hawaii Plaintiff and Hawaii Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Hawaii Plaintiff or Hawaii Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them;

because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

965. Hawaii Plaintiff, and members of the Hawaii Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

966. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Hawaii Plaintiff (as set forth above) and members of the Hawaii Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Hawaii Plaintiff and Hawaii Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Hawaii Plaintiff and Hawaii Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Hawaii Plaintiff and Hawaii Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

967. Accordingly, pursuant to the Haw. Rev. Stat. § 481A-1, Hawaii Plaintiff and Hawaii Subclass members are entitled to injunctive relief and all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.



**COUNT 28 – VIOLATIONS OF IDAHO CONSUMER PROTECTION ACT**

**Idaho Code § 48-601, *et seq.***

**On Behalf of the Idaho Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

968. Plaintiff Savoure (“Idaho Plaintiff”) realleges and incorporates by reference all preceding allegations as though fully set forth herein.

969. Idaho Plaintiff brings this cause of action individually and on behalf of the members of the Idaho Subclass.

970. This claim is brought against the Philips Defendants.

971. The Idaho Consumer Protection Act was created to protect Idaho consumers from deceptive and unfair business practices.

972. Idaho Plaintiff and Idaho Subclass members are persons who purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

973. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Idaho. In addition, Philips, among other things, sold the Recalled Devices in Idaho, shipped Recalled Devices to Idaho, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Idaho.

974. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

975. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

976. Philips' conduct described herein constitutes use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Idaho, making it unlawful under Idaho Code § 48-601, *et seq.*

977. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have; (b) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; (c) engaging in any act or practice that is otherwise misleading, false, or deceptive to the consumer; and (d) engaging in any unconscionable method, act or practice in the conduct of trade or commerce. *See* Idaho Code § 48-603, *et seq.*

978. Philips' conduct constituted, among other things, the following unconscionable methods, acts or practices in the conduct of trade or commerce: (a) Philips knowingly or with reason to know, took advantage of consumers reasonably unable to protect their interests because of physical infirmity, ignorance, illiteracy, inability to understand the language of the agreement or similar factor; (b) Philips knowingly or with reason to know, induced consumers to enter into

transactions that were excessively one-sided in favor of Philips; and (c) the sales conduct or pattern of sales conduct by Philips would outrage or offend the public conscience. Idaho Code § 48-603C.

979. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Idaho Plaintiff. Ordinary consumers, including Idaho Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Idaho Plaintiff's, as well as other Idaho Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

980. Philips owed Idaho Plaintiff and Idaho Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Idaho Plaintiff or Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

981. Idaho Plaintiff and Idaho Subclass members justifiably relied on the material misrepresentations and/or omissions made by Philips and purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Idaho Code § 48-601, *et seq.* Idaho Plaintiff and Idaho Subclass members acted as reasonable consumers would have acted

under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

982. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Idaho Plaintiff (as set forth above) and members of the Idaho Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Idaho Plaintiff and Idaho Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Idaho Plaintiff and Idaho Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

983. Accordingly, pursuant to Idaho Code § 48-601, *et seq.*, Idaho Plaintiff and Idaho Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or (b) the cost to replace the Recalled Devices, and (c) other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Idaho Plaintiff and Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 29 – VIOLATIONS OF ILLINOIS CONSUMER FRAUD AND DECEPTIVE  
BUSINESS PRACTICES ACT**

**815 Ill. Comp. Stat. Ann. § 505/1, *et seq.***

**On Behalf of the Illinois Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

984. Plaintiffs Baran, Brooks, Rootberg, and MSP (“Illinois Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

985. Illinois Plaintiffs bring this cause of action individually and on behalf of the members of the Illinois Subclass.

986. This claim is brought against the Philips Defendants.

987. The Illinois Consumer Fraud and Deceptive Business Practices Act was created to protect Illinois consumers from deceptive and unfair business practices.

988. Illinois Plaintiffs and Illinois Subclass members are persons who purchased, leased, or reimbursed payment for Recalled Devices for personal purposes and household use.

989. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Illinois. In addition, Philips, among other things, sold the Recalled Devices in Illinois, shipped Recalled Devices to Illinois, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Illinois.

990. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and

other healthcare professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

991. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

992. Philips' conduct constitutes use or employment of deception, fraud, false pretense, false promise, misrepresentation and the concealment, suppression, or omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Illinois, with the intention that Plaintiffs and Illinois Subclass members would rely on such concealment, suppression, or omission of material facts in deciding to purchase, lease, or reimburse payment for the Recalled Devices, making it unlawful under 815 Ill. Comp. Stat. Ann. § 505/1, *et seq.*

993. Philips' prohibited deceptive business practices occurred primarily and substantially within Illinois.

994. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Illinois Plaintiffs. Ordinary consumers, including Illinois Plaintiffs, would have found it material to their purchasing, leasing, or reimbursement decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences.

Knowledge of those facts would have been a substantial factor in Illinois Plaintiffs', as well as Illinois Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

995. Philips owed Illinois Plaintiffs and Illinois Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Illinois Plaintiffs or Illinois Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

996. Illinois Plaintiffs and Illinois Subclass members justifiably relied on the concealment, suppression, or omission of material facts made by Philips, and reasonable consumers would have been expected to rely upon these misrepresentations and/or omissions, in part, because they are misrepresentations and/or omissions that impact seriously on a consumer's health and well-being.

997. Philips' conduct actually and proximately caused actual damages to Illinois Plaintiffs (as set forth above) and members of the Illinois Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Illinois Plaintiffs and Illinois Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Illinois Plaintiffs and Illinois Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done, in part, because they are omissions that impact seriously on consumer's health and well-being. Illinois Plaintiffs and Illinois Subclass members acted as reasonable consumers

would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

998. Accordingly, pursuant to 815 Ill. Comp. Stat. Ann. § 505/1, *et seq.*, Illinois Plaintiffs and Illinois Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Illinois Plaintiffs and Illinois Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 30 – VIOLATIONS OF ILLINOIS UNIFORM DECEPTIVE TRADE  
PRACTICES ACT**

**815 Ill. Comp. Stat. Ann. § 5105/1, *et seq.***

**On Behalf of the Illinois Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

999. Plaintiffs Baran, Brooks, Rootberg, and MSP ("Illinois Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1000. Illinois Plaintiffs bring this cause of action individually and on behalf of the members of the Illinois Subclass.

1001. This claim is brought against the Philips Defendants.

1002. The Illinois Uniform Deceptive Trade Practices Act was created to protect Illinois consumers from deceptive and unfair advertising practices.



1003. Illinois Plaintiffs and Illinois Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes and household use.

1004. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Illinois. In addition, Philips, among other things, sold the Recalled Devices in Illinois, shipped Recalled Devices to Illinois, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Illinois.

1005. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1006. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1007. Philips' conduct described herein constitutes, among other things, the following prohibited deceptive trade practices: (a) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have; (b)

representing that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, when they are of another; (c) advertising goods or services with intent not to sell them as advertised; and (d) engaging in any other conduct which similarly creates a likelihood of confusion or misunderstanding. 815 Ill. Comp. Stat. Ann. § 510/2.

1008. Philips' prohibited deceptive trade practices occurred primarily and substantially within Illinois.

1009. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Illinois Plaintiffs. Ordinary consumers, including Illinois Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Illinois Plaintiffs', as well as other Illinois Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1010. Philips owed Illinois Plaintiffs and Illinois Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Illinois Plaintiffs or Illinois Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1011. Illinois Plaintiffs and Illinois Subclass members justifiably relied on the misrepresentations and/or omissions by Philips, and reasonable consumers would have been

expected to rely upon these misrepresentations and/or omissions, in part, because they are misrepresentations and/or omissions that impact seriously on a consumer's health and well-being.

1012. Philips' conduct actually and proximately caused actual damages to Illinois Plaintiffs (as set forth above) and members of the Illinois Subclass. Absent Philips' deceptive and/or fraudulent conduct, Illinois Plaintiffs and Illinois Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Illinois Plaintiffs and Illinois Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Illinois Plaintiffs and Illinois Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damage.

1013. Accordingly, pursuant to 815 Ill. Comp. Stat. Ann. § 5105/1, *et seq.*, Illinois Plaintiffs and the Illinois Subclass members are entitled to equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 31 – VIOLATIONS OF INDIANA DECEPTIVE CONSUMER SALES ACT**

**Ind. Code § 24-5-0.5-1, *et seq.***

**On Behalf of the Indiana Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1014. Plaintiffs Diane Anderson, Clark, and Ohio Carpenters ("Indiana Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1015. Indiana Plaintiffs bring this cause of action individually and on behalf of the members of the Indiana Subclass.

1016. This claim is brought against the Philips Defendants.

1017. The Indiana Deceptive Consumer Sales Act (“IDCSA”) was created to protect Indiana consumers from deceptive and unfair business practices.

1018. Indiana Plaintiffs and Indiana Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1019. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Indiana. In addition, Philips, among other things, sold the Recalled Devices in Indiana, shipped Recalled Devices to Indiana, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Indiana.

1020. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1021. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1022. Philips' conduct constitutes the knowing use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Indiana, making it unlawful under Ind. Code § 24-5-0.5-1, *et seq.*

1023. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) representing that such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses, or benefits it does not have which the supplier knows or should reasonably know it does not have; (b) representing that such subject of a consumer transaction is of a particular standard, quality, grade, style, or model, if it is not and if the supplier knows or should reasonably know that it is not; (c) representing that a specific price advantage exists as to such subject of a consumer transaction, if it does not and if the supplier knows or should reasonably know that it does not; and (d) representing that such consumer transaction involves or does not involve a warranty, a disclaimer of warranties, or other rights, remedies, or obligations, if the representation is false and if the supplier knows or should reasonably know that the representation is false. Ind. Code § 24-5-0.5-3.

1024. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Indiana Plaintiffs. Ordinary consumers, including Indiana Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have

been a substantial factor in Indiana Plaintiffs', as well as other Indiana Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1025. Philips owed Indiana Plaintiffs and Indiana Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Indiana Plaintiffs or Indiana Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1026. Indiana Plaintiffs and Indiana Subclass members justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1027. Philips' conduct actually and proximately caused actual damages to Indiana Plaintiffs (as set forth above) and members of the Indiana Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Indiana Plaintiffs and Indiana Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Indiana Plaintiffs and Indiana Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Indiana Plaintiffs and Indiana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1028. Accordingly, pursuant to Ind. Code § 24-5-0.5-1, *et seq.*, Indiana Plaintiffs and Indiana Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease, and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Indiana Plaintiffs and Indiana Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

1029. Philips' conduct is "incurable" as defined by the IDCSEA because it was done as part of a scheme with the intent to defraud, mislead, and engage in unfair business practices.

1030. Because Philips' conduct is "incurable" as defined by the IDCSEA, no pre-suit notice was required. To the extent that any pre-suit notice was purportedly required, Indiana Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. These letters put Philips on notice of the demands of the Indiana Plaintiffs and Indiana Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Indiana Plaintiffs and Indiana Subclass members for all the economic losses they have suffered as a result of Philips' conduct. Philips has failed to remedy its unlawful

misconduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of Indiana. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 32 – VIOLATIONS OF IOWA PRIVATE RIGHT OF ACTION FOR  
CONSUMER FRAUDS ACT**

**Iowa Code § 714H.1, *et seq.***

**On Behalf of the Iowa Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1031. Plaintiffs Abarr, Diamond, and Wilson (“Iowa Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1032. Iowa Plaintiffs bring this cause of action individually and on behalf of the members of the Iowa Subclass.

1033. This claim is brought against the Philips Defendants.

1034. The Iowa Private Right of Action for Consumer Frauds Act was created to protect Iowa consumers from deceptive and unfair trade practices.

1035. Iowa Plaintiffs and Iowa Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1036. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Iowa. In addition, Philips, among other things, sold the Recalled Devices in Iowa, shipped Recalled Devices to Iowa, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Iowa.

1037. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as



they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1038. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1039. Philips' conduct constitutes the knowing act, use or employment of unfair practice, deception, fraud, false pretense, or false promise, or the misrepresentation, concealment, suppression, or omission of a material fact in connection with the advertisement, sale or lease of consumer merchandise, the Recalled Devices, in trade or commerce in Iowa, and was made with the intention that the Iowa Plaintiffs and Iowa Subclass members rely on such conduct in purchasing or leasing the Recalled Devices, making it unlawful under Iowa Code § 714H.1, *et seq.*

1040. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Iowa Plaintiffs. Ordinary consumers, including Iowa Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have

been a substantial factor in Iowa Plaintiffs', as well as other Iowa Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1041. Philips owed Iowa Plaintiffs and Iowa Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Iowa Plaintiffs or Iowa Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1042. Iowa Plaintiffs and Iowa Subclass members justifiably relied on the material misrepresentations and/or omissions made by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1043. Philips' conduct actually and proximately caused Iowa Plaintiffs (as set forth above) and members of the Iowa Subclass to suffer an ascertainable loss of money or property. Absent Philips' unfair, deceptive and/or fraudulent conduct, Iowa Plaintiffs and Iowa Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Iowa Plaintiffs and Iowa Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Iowa Plaintiffs and Iowa Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1044. Accordingly, pursuant to Iowa Code § 714H.1, *et seq.*, Iowa Plaintiffs and Iowa Subclass members are entitled to recover their actual damages that are reasonably ascertainable in amount. Their damages can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Iowa Plaintiffs and Iowa Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 33 – VIOLATIONS OF KANSAS CONSUMER PROTECTION ACT**

**Kan. Stat. § 50-623, *et seq.***

**On Behalf of the Kansas Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1045. Plaintiff Cathers ("Kansas Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1046. Kansas Plaintiff brings this cause of action individually and on behalf of the members of the Kansas Subclass.

1047. This claim is brought against the Philips Defendants.

1048. The Kansas Consumer Protection Act was created to protect Kansas consumers from deceptive and unfair business practices.

1049. Kansas Plaintiff and Kansas Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1050. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Kansas. In addition, Philips, among other things, sold the Recalled Devices in Kansas, shipped Recalled Devices to Kansas, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Kansas.

1051. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1052. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1053. Philips' conduct constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Kansas, making it unlawful under Kan. Stat. § 50-623.

1054. Philips' conduct constituted, among other things, the following prohibited, deceptive and unfair business practices: (a) knowingly representing that property or services have sponsorship, approval, accessories, characteristics, ingredients, uses, benefits or quantities that they do not have; (b) knowingly representing that property or services are of particular standard, quality, grade, style or model, if they of another which differs materially from the representation; (c) knowingly representing that property or services has uses, benefits or characteristics unless the supplier relied upon and possesses a reasonable basis for making such representation; (d) knowingly representing that use, benefit or characteristic of property or services has been proven or otherwise substantiated unless the supplier relied upon and possesses the type and amount of proof or substantiation represented to exist; (e) the willful use, in any oral or written representation, of exaggeration, falsehood, innuendo or ambiguity as to a material fact; and (f) the willful failure to state a material fact, or the willful concealment, suppression, or omission of a material fact. Kan. Stat. § 50-626.

1055. Philips' conduct constituted, among other things, the following unconscionable methods, acts or practices in the conduct of trade or commerce: (a) Philips knowingly or with reason to know, took advantage of the inability of the consumer reasonably to protect the consumer's interests because of the consumer's physical infirmity, ignorance, illiteracy, inability to understand the language of an agreement or similar factor; (b) Philips knew or had reason to know the consumer was unable to receive a material benefit from the subject of the transaction; and (c) Philips knew or had reason to know the transaction the supplier induced the consumer to enter into was excessively one sided in favor of the supplier; and (d) Philips knew or had reason to know it made a misleading statement of opinion on which the consumer was likely to rely to the consumer's detriment. Kan. Stat. § 50-627.

1056. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Kansas Plaintiff. Ordinary consumers, including Kansas Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Kansas Plaintiff's, as well as other Kansas Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1057. Philips owed Kansas Plaintiff and Kansas Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Kansas Plaintiff or Kansas Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1058. Kansas Plaintiff and members of the Kansas Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1059. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Kansas Plaintiff (as set forth above) and members of the Kansas Subclass. Absent Philips' unfair, deceptive, unconscionable and/or fraudulent conduct, Kansas Plaintiff and Kansas Subclass members would have behaved differently and would not have purchased,

leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Kansas Plaintiff and Kansas Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Kansas Plaintiff and Kansas Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1060. Accordingly, pursuant to Kan. Stat. § 50-623, Kansas Plaintiff and Kansas Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Kansas Plaintiff and Kansas Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 34 – VIOLATIONS OF KENTUCKY CONSUMER PROTECTION ACT**

***Ky. Rev. Stat. § 367.110, et seq.***

**On Behalf of the Kentucky Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1061. Plaintiffs Ratliff and Ohio Carpenters ("Kentucky Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1062. Kentucky Plaintiffs bring this cause of action individually and on behalf of the members of the Kentucky Subclass.

1063. This claim is brought against the Philips Defendants.

1064. The Kentucky Consumer Protection Act was created to protect Kentucky consumers from deceptive and unfair business practices.

1065. Kentucky Plaintiff and Kentucky Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1066. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Kentucky. In addition, Philips, among other things, sold the Recalled Devices in Kentucky, shipped Recalled Devices to Kentucky, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Kentucky.

1067. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1068. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices. Philips continued its unfair and deceptive conduct after Kentucky Plaintiffs



and Kentucky Subclass members purchased, leased, or reimbursed payment for Recalled Devices.

1069. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Kentucky, making it unlawful under Ky. Rev. Stat. § 367.110.

1070. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Kentucky Plaintiff. Ordinary consumers, including Kentucky Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Kentucky Plaintiff's, as well as other Kentucky Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1071. Philips owed Kentucky Plaintiff and Kentucky Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Kentucky Plaintiff or Kentucky Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1072. Kentucky Plaintiff and Kentucky Subclass members justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have

been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1073. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Kentucky Plaintiff (as set forth above) and members of the Kentucky Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Kentucky Plaintiff and Kentucky Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Kentucky Plaintiff and Kentucky Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Kentucky Plaintiff and Kentucky Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1074. Accordingly, pursuant to Ky. Rev. Stat. § 367.110, Kentucky Plaintiff and Kentucky Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Kentucky Plaintiff and Kentucky Subclass members are entitled to all available statutory exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 35 – VIOLATIONS OF REDHIBITION (INCLUDING WARRANTY OF FITNESS)**

**Pursuant to La. Civ. Code art. 2520, *et seq.***

**On behalf of the Louisiana Subclass, except for Class Members who purchased or leased a Recalled Device for business use only**

1075. Plaintiffs Baudoin, Couch, Gilliard-Gunter, Susan Martin, and Romas (“Louisiana Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1076. Louisiana Plaintiffs bring this cause of action individually and on behalf of the members of the Louisiana Subclass

1077. This claim is brought against the Philips Defendants.

1078. At all times herein, Philips was the manufacturer of the Recalled Devices sold to Louisiana Plaintiffs.

1079. At the time the Recalled Devices were sold and/or delivered to Louisiana Plaintiffs herein, Philips had reason to know and were in fact aware that Louisiana Plaintiffs and Louisiana Subclass members intended to use the devices to treat sleep apnea or for other reasons related to breathing.

1080. The Recalled Devices manufactured, distributed and/or sold by Philips were not reasonably fit for their ordinary and intended use and purpose.

1081. Philips is therefore liable to Louisiana Plaintiffs and Louisiana Subclass members for all damages reasonable in the premises, in accordance with La. Civ. Code art. 2524.

1082. The Recalled Devices manufactured, distributed and/or sold by Philips contained redhibitory defects at the time of sale and/or delivery, including the propensity to degrade and/or emit potentially harmful substances, as described above.

1083. The Recalled Devices manufactured, distributed and/or sold by Philips contained redhibitory defects at the time of sale and/or delivery that render the devices so useless and/or inconvenient that it must be presumed that Louisiana Plaintiffs and Louisiana Subclass members would not have purchased, leased, leased, or reimbursed payment for the Recalled Devices had they known of the redhibitory defects.

1084. Philips is conclusively presumed to know of the Defect in the Recalled Devices it manufactured.

1085. In addition, it is believed and alleged that Philips knew of the Defect in the devices at the time the Recalled Devices were sold and/or delivered to Louisiana Plaintiffs and Louisiana Subclass members, and as such Philips is considered to be a seller in bad faith.

1086. The defective condition affecting the Recalled Devices was present at the time of their sale and/or delivery to Louisiana Plaintiffs and Louisiana Subclass members.

1087. The defective condition affecting the Recalled Devices was neither known nor could have been discovered by Louisiana Plaintiffs at the time the Recalled Devices were sold and/or delivered to them.

1088. As a result of Philips' Recalled Devices' redhibitory defects, Louisiana Plaintiffs and Louisiana Subclass members have suffered actual damages in that: each Recalled Device they purchased, leased, or reimbursed payment for is worth less (\$0.00) than the price they paid or reimbursed payment for, and they would not have purchased, leased, or reimbursed payment for the Recalled Devices at all had they known of the health risks associated with the use of the Recalled Devices.

1089. In addition, because Philips was aware at the time the Recalled Devices were sold and/or delivered to Louisiana Plaintiffs and Louisiana Subclass members that Louisiana

Plaintiffs intended to use the Recalled Devices to treat sleep apnea or for other reasons related to breathing and that the Recalled Devices were not fit for Louisiana Plaintiffs' particular purposes, Philips breached the contract of sale in bad faith.

1090. Philips is therefore liable to Louisiana Plaintiffs and Louisiana Subclass members for a return of the purchase or lease price or reimbursement payment (with interest from the time it was paid), insurance co-payments, reimbursement of reasonable expenses occasioned by the sale and those incurred for the preservation of the Recalled Devices and associated items, for damages, including any and all economic damages, cost of procuring a replacement device, mental anguish, fear and fright, inconvenience, and/or loss of use, and for reasonable attorneys' fees, in accordance with La. Civ. Code art. 2545.

**COUNT 36 – VIOLATIONS OF LOUISIANA UNFAIR TRADE PRACTICES AND  
CONSUMER PROTECTION LAW**

**La. Rev. Stat. Ann. § 51:1401, *et seq.***

**On Behalf of the Louisiana Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1091. Plaintiffs Baudoin, Couch, Gilliard-Gunter, Susan Martin, and Romas ("Louisiana Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1092. Louisiana Plaintiffs bring this cause of action individually and on behalf of the members of the Louisiana Subclass.

1093. This claim is brought against the Philips Defendants.

1094. The Louisiana Unfair Trade Practices and Consumer Protection Law was created to protect Louisiana consumers from deceptive and unfair business practices.

1095. Louisiana Plaintiff and Louisiana Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1096. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Louisiana. In addition, Philips, among other things, sold the Recalled Devices in Louisiana, shipped Recalled Devices to Louisiana, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Louisiana.

1097. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1098. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1099. Philips' conduct described herein constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Louisiana, and was made with the intention that Louisiana Plaintiffs and Louisiana Subclass members would rely upon such

conduct in purchasing or leasing the Recalled Devices, making it unlawful under La. Rev. Stat. Ann. § 51:1401.

1100. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Louisiana Plaintiffs. Ordinary consumers, including Louisiana Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Louisiana Plaintiffs', as well as other Louisiana Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1101. Philips owed Louisiana Plaintiffs and Louisiana Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Louisiana Plaintiffs or Louisiana Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1102. Louisiana Plaintiffs and Louisiana Subclass members justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these misrepresentations and/or omissions, in part, because they are misrepresentations and/or omissions that impact seriously on a consumer's health and well-being.

1103. Philips' conduct actually and proximately caused an ascertainable loss of money or movable property to Louisiana Plaintiffs (as set forth above) and members of the Louisiana Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Louisiana Plaintiffs and Louisiana Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Louisiana Plaintiffs and Louisiana Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Louisiana Plaintiffs and Louisiana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1104. Accordingly, pursuant to La. Rev. Stat. Ann. § 51:1401, Louisiana Plaintiffs and Louisiana Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Louisiana Plaintiffs and Louisiana Subclass members are entitled to all available statutory exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.



**COUNT 37 – VIOLATIONS OF MAINE UNFAIR TRADE PRACTICES ACT**

**5 Me. Rev. Stat. Ann. § 205-A, *et seq.***

**On Behalf of the Maine Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1105. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz (“Maine Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1106. Maine Plaintiffs bring this cause of action individually and on behalf of the members of the Maine Subclass.

1107. This claim is brought against the Philips Defendants.

1108. The Maine Unfair Trade Practices Act was created to protect Maine consumers from deceptive and unfair business practices.

1109. The Recalled Devices are “goods” or “personal property” within the meaning of the Maine Unfair Trade Practices Act.

1110. Maine Plaintiffs and Maine Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1111. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Maine. In addition, Philips, among other things, sold the Recalled Devices in Maine, shipped Recalled Devices to Maine, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Maine.

1112. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and

other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1113. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, misleading, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1114. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Maine, making it unlawful under 5 Me. Rev. Stat. Ann § 205-A.

1115. Philips' conduct was unfair, fraudulent, deceptive, and/or unconscionable because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Maine Plaintiffs. Ordinary consumers, including Maine Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Maine Plaintiffs', as well as Maine Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1116. Philips owed Maine Plaintiffs and Maine Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along

with PolyTech and potentially other unnamed parties who are not Maine Plaintiffs or Maine Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1117. Maine Plaintiffs and members of the Maine Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these statements and/or omissions, in part, because they are statements and/or omissions that impact seriously on a consumer's health and well-being.

1118. Philips' conduct actually and proximately caused loss of money or property to Maine Plaintiffs (as set forth above) and members of the Maine Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Maine Plaintiffs and Maine Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Maine Plaintiffs and Maine Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Maine Plaintiffs and Maine Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages

1119. Accordingly, pursuant to 5 Me. Rev. Stat. Ann § 205-A, Maine Plaintiffs and Maine Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their

prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Maine Plaintiffs and Maine Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary, and all such other relief as the Court deems proper.

1120. To the extent that any pre-suit notice was purportedly required, Maine Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. These letters put Philips on notice of the demands of the Maine Plaintiffs and Maine Subclass members and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Maine Plaintiffs and Maine Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of Maine. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 38 – VIOLATIONS OF MAINE UNIFORM DECEPTIVE TRADE PRACTICES  
ACT**

**10 Me. Rev. Stat. tit. § 1211, *et seq.***

**On Behalf of the Maine Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1121. Plaintiffs Julie Barrett, Peter Barrett, Margoles, and Schwartz (“Maine Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1122. Maine Plaintiffs bring this cause of action individually and on behalf of the members of the Maine Subclass.

1123. This claim is brought against the Philips Defendants.

1124. The Maine Uniform Deceptive Trade Practices Act was created to protect Maine consumers from deceptive and/or unfair business practices.

1125. Maine Plaintiffs and Maine Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1126. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Maine. In addition, Philips, among other things, sold the Recalled Devices in Maine, shipped Recalled Devices to Maine, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Maine.

1127. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health riskS to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and

other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1128. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, misleading, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1129. Philips' conduct constitutes the act, use or employment of conduct in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Maine, which conduct created confusion or misunderstanding on the part of Maine Plaintiffs and Maine Subclass Members, making it unlawful under 10 Me. Rev. Stat. tit. § 1121.

1130. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services; (b) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have, or that a person has a sponsorship, approval, status, affiliation or connection that he does not have; (c) represents that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another; (d) advertises goods or services with intent not to sell them as advertised; and (e) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

1131. Philips' conduct was unfair, fraudulent, and/or deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Maine Plaintiffs. Ordinary consumers, including Maine Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Maine Plaintiffs', as well as other Maine Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1132. Philips owed Maine Plaintiffs and Maine Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Maine Plaintiffs or Maine Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1133. Maine Plaintiffs and members of the Maine Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1134. Philips' conduct actually and proximately caused loss of money or property to Maine Plaintiffs (as set forth above) and members of the Maine Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Maine Plaintiffs and Maine Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the

Recalled Devices. Philips' omissions induced Maine Plaintiffs and Maine Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Maine Plaintiffs and Maine Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1135. Accordingly, pursuant to the 10 Me. Rev. Stat. tit. § 1211, *et seq.*, Maine Plaintiffs and the Maine Subclass members are entitled to equitable relief necessary or proper to protect them from Philips' unlawful conduct and to award all appropriate damages and attorneys' fees and costs.

**COUNT 39 – VIOLATIONS OF MARYLAND CONSUMER PROTECTION ACT**

**Md. Code Com. Law § 13-101, *et seq.***

**On Behalf of the Maryland Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1136. Plaintiff Dzierzanowski ("Maryland Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1137. Maryland Plaintiff brings this cause of action individually and on behalf of the members of the Maryland Subclass.

1138. This claim is brought against the Philips Defendants.

1139. The Maryland Consumer Protection Act was created to protect Maryland consumers from unfair, abusive, and/or deceptive trade practice trade practices.

1140. Maryland Plaintiff and Maryland Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1141. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Maryland. In addition, Philips, among other things, sold the



Recalled Devices in Maryland, shipped Recalled Devices to Maryland, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Maryland.

1142. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1143. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, fraudulent, abusive, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1144. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Maryland, making it unlawful under Md. Code Com. Law § 1301, *et seq.*

1145. Philips' conduct constituted, among other things, the following prohibited unfair, abusive, or deceptive trade practices: (a) misrepresenting that the Recalled Devices have

characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) failure to state a material fact if the failure deceives or tends to deceive; (d) advertisement or offer of consumer goods, consumer realty, or consumer services without intent to sell, lease, or rent them as advertised or offered; (e) deception, fraud, false pretense, false premise, misrepresentation, knowing concealment, suppression, or omission of any material fact with the intent that a consumer rely on the same; and/or (f) engaging in fraudulent and deceptive conduct as described herein.

1146. Philips' conduct was unfair, fraudulent, abusive, and/or deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Maryland Plaintiff. Ordinary consumers, including Maryland Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Maryland Plaintiff's, as well as other Maryland Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1147. Philips owed Maryland Plaintiff and Maryland Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Maryland Plaintiff or Maryland Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them;

because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1148. Maryland Plaintiff and members of the Maryland Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1149. Philips' conduct actually and proximately caused loss of money or property to Maryland Plaintiff (as set forth above) and members of the Maryland Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Maryland Plaintiff and Maryland Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Maryland Plaintiff and Maryland Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Maryland Plaintiff and the Maryland Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1150. Accordingly, pursuant to Md. Code Com. Law § 1301, *et seq.*, Maryland Plaintiff and Maryland Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Maryland Plaintiff and

Maryland Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 40 – VIOLATIONS OF MASSACHUSETTS REGULATION OF BUSINESS  
PRACTICES FOR CONSUMERS**

**Mass. Gen. L. Ch. 93A § 1-11, *et seq.***

**On Behalf of the Massachusetts Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1151. Plaintiffs Bellotti, Conley, Whaley, and MSP ("Massachusetts Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1152. Massachusetts Plaintiffs bring this cause of action individually and on behalf of the members of the Massachusetts Subclass.

1153. This claim is brought against the Philips Defendants.

1154. The Massachusetts Regulation of Business Practices for Consumers Act was created to protect Massachusetts consumers from unfair and/or deceptive trade practices.

1155. Massachusetts Plaintiffs and Massachusetts Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1156. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Massachusetts. In addition, Philips, among other things, sold the Recalled Devices in Massachusetts, shipped Recalled Devices to Massachusetts, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Massachusetts.

1157. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in

that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1158. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, fraudulent, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1159. Philips' conduct constitutes the knowing and intentional act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Massachusetts, making it unlawful under Mass. Gen. L. Ch. 93A § 1-11, *et seq.*

1160. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1161. Philips' conduct constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Massachusetts Plaintiffs. Ordinary consumers, including Massachusetts Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Massachusetts Plaintiffs', as well as other Massachusetts Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1162. Philips owed Massachusetts Plaintiffs and Massachusetts Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Massachusetts Plaintiffs or Massachusetts Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1163. Massachusetts Plaintiffs and members of the Massachusetts Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1164. Philips' conduct actually and proximately caused loss of money or property to Massachusetts Plaintiffs (as set forth above) and members of the Massachusetts Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Massachusetts Plaintiffs and Massachusetts Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Massachusetts Plaintiffs and Massachusetts Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Massachusetts Plaintiffs and Massachusetts Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing for the Recalled Devices) that resulted in the damages.

1165. Accordingly, pursuant to Mass. Gen. L. Ch. 93A § 1-11, *et seq.*, Massachusetts Plaintiffs and Massachusetts Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Massachusetts Plaintiffs and Massachusetts Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

1166. To the extent that any pre-suit notice was purportedly required, Massachusetts Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Additional notice letters were served on Philips before this MDL was formed and months before the filing of any Consolidated Class Action Complaint for Economic Losses by plaintiffs who brought putative class actions that have been consolidated in this MDL. These letters put Philips on notice of the demands of the Massachusetts Plaintiffs and Massachusetts Subclass, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Massachusetts Plaintiffs and Massachusetts Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 41 – VIOLATIONS OF MICHIGAN CONSUMER PROTECTION ACT**

**Mich. Comp. Laws Ann. § 445.901, *et seq.***

**On Behalf of the Michigan Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1167. Plaintiffs Wilks, Ohio Carpenters, and MSP ("Michigan Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1168. Michigan Plaintiffs bring this cause of action individually and on behalf of the members of the Michigan Subclass.

1169. This claim is brought against the Philips Defendants.



1170. The Michigan Consumer Protection Act was created to protect Michigan consumers from unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce.

1171. Michigan Plaintiffs and Michigan Subclass members purchases, leased, or reimbursed payments for Recalled Devices for personal purposes.

1172. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Michigan. In addition, Philips, among other things, sold the Recalled Devices in Michigan, shipped Recalled Devices to Michigan, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Michigan.

1173. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1174. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, unconscionable, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1175. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Michigan, made with the intention that Plaintiff and Michigan Subclass members would rely upon such conduct in purchasing, leasing, or reimbursing payment for the Recalled Devices, making it unlawful under Mich. Comp. Law Ann. § 445.901, *et seq.*

1176. Philips' conduct constituted, among other things, the following unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce: (a) causing a probability of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services; (b) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has sponsorship, approval, status, affiliation, or connection that he or she does not have; (c) representing that goods or services are of a particular standard, quality, or grade; (d) advertising or representing goods or services with intent not to dispose of those goods or services as advertised or represented; (e) failing to reveal a material fact, the omission of which tends to mislead or deceive the consumer, and which fact could not reasonably be known by the consumer; (f) making a representation of fact or statement of fact material to the transaction such that a person reasonably believes the represented or suggested state of affairs to be other than it actually is; and (g) failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner.

1177. Philips' conduct was unfair, unconscionable, or deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to

deceive and, in fact, did deceive, ordinary consumers, including Michigan Plaintiffs. Ordinary consumers, including Michigan Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Michigan Plaintiffs', as well as Michigan Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1178. Philips owed Michigan Plaintiffs and Michigan Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Michigan Plaintiffs or Michigan Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1179. Michigan Plaintiffs and members of the Michigan Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1180. Philips' conduct actually and proximately caused loss of money or property to Michigan Plaintiffs (as set forth above) and members of the Michigan Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Michigan Plaintiffs and Michigan Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Michigan Plaintiffs and Michigan Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would

not otherwise have done. Michigan Plaintiffs and Michigan Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, reimbursing for the Recalled Devices) that resulted in the damages

1181. Accordingly, pursuant to Mich. Comp. Law Ann. § 445.901, *et seq.*, Michigan Plaintiffs and Michigan Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Michigan Plaintiffs and Michigan Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 42 – VIOLATIONS OF MINNESOTA PREVENTION OF CONSUMER FRAUD  
ACT**

**Minn. Stat. § 325F.68, *et seq.***

**On Behalf of the Minnesota Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1182. Plaintiffs Boudreau and Mold ("Minnesota Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1183. Minnesota Plaintiffs bring this cause of action individually and on behalf of the members of the Minnesota Subclass.

1184. This claim is brought against the Philips Defendants.

1185. The Minnesota Consumer Fraud Act was created to protect Minnesota consumers from deceptive and unfair sales practices.

1186. Minnesota Plaintiffs and Minnesota Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1187. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Minnesota. In addition, Philips, among other things, sold the Recalled Devices in Minnesota, shipped Recalled Devices to Minnesota, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Minnesota.

1188. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1189. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading, fraudulent, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1190. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale of merchandise, the Recalled Devices, in trade or commerce in Minnesota, made with the intention that Minnesota Plaintiffs and Minnesota Subclass members would rely upon such conduct in purchasing, leasing, or reimbursing payment for the Recalled Devices, making it unlawful under Minn. Stat. § 325F.68, *et seq.*

1191. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Minnesota Plaintiffs. Ordinary consumers, including Minnesota Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Minnesota Plaintiffs', as well as Minnesota Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1192. Philips owed Minnesota Plaintiffs and Minnesota Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Minnesota Plaintiffs or Minnesota Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1193. Minnesota Plaintiffs and members of the Minnesota Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these statements and/or omissions, in part, because they are statements and/or omissions that impact seriously on a consumer's health and well-being.

1194. Philips' conduct actually and proximately caused loss of money or property to Minnesota Plaintiffs (as set forth above) and members of the Minnesota Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Minnesota Plaintiffs and Minnesota Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Minnesota Plaintiffs and Minnesota Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Minnesota Plaintiffs and Minnesota Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1195. Accordingly, pursuant to Minn. Stat. § 325F.68, *et seq.*, Minnesota Plaintiffs and Minnesota Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Minnesota Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and

attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 43 – VIOLATIONS OF MINNESOTA FALSE ADVERTISING ACT**

**Minn. Stat. § 325F.67, *et seq.***

**On Behalf of the Minnesota Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1196. Plaintiffs Boudreau and Mold ("Minnesota Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1197. Minnesota Plaintiffs bring this cause of action individually and on behalf of the members of the Minnesota Subclass.

1198. This claim is brought against the Philips Defendants.

1199. The Minnesota False Advertising Statute was created to protect Minnesota consumers from deceptive and unfair advertising.

1200. Minnesota Plaintiffs and Minnesota Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1201. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Minnesota in an effort to increase the number of users of the Recalled Devices in Minnesota and increase its sales of the Recalled Devices in Minnesota. In addition, Philips, among other things, sold the Recalled Devices in Minnesota, shipped Recalled Devices to Minnesota, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Minnesota.

1202. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health riskS to users who would potentially be inhaling toxic fumes as



they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1203. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation of off-gassing of the PE-PUR. This material omission was false, misleading, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1204. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Minnesota Plaintiffs. Ordinary consumers, including Minnesota Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Minnesota Plaintiffs', as well as other Minnesota Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1205. Philips owed Minnesota Plaintiffs and Minnesota Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Minnesota Plaintiffs or Minnesota Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively

concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1206. Minnesota Plaintiffs and members of the Minnesota Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1207. Philips' conduct actually and proximately caused loss of money or property to Minnesota Plaintiffs (as set forth above) and members of the Minnesota Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Minnesota Plaintiffs and Minnesota Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Minnesota Plaintiffs and Minnesota Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Minnesota Plaintiffs and Minnesota Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1208. Accordingly, pursuant to Minn. Stat. § 325F.67, *et seq.*, Minnesota Plaintiffs and Minnesota Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and

consequential damages. In addition, given the nature of Philips' conduct, Minnesota Plaintiffs and Minnesota Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 44 – VIOLATIONS OF MISSISSIPPI CONSUMER PROTECTION ACT**

**Miss. Code § 75-24-1, et seq.**

**On Behalf of the Mississippi Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1209. Plaintiffs Godeaux, Rankin and Tucker ("Mississippi Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1210. Mississippi Plaintiffs bring this cause of action individually and on behalf of the members of the Mississippi Subclass.

1211. This claim is brought against the Philips Defendants.

1212. The Mississippi Consumer Protection Act was created to protect Mississippi consumers from deceptive and unfair business practices.

1213. Mississippi Plaintiffs and Mississippi Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1214. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Mississippi. In addition, Philips, among other things, sold the Recalled Devices in Mississippi, shipped Recalled Devices to Mississippi, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Mississippi.

1215. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in

that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1216. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was unfair, misleading, and/or deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1217. Philips' conduct described herein constitutes the knowing and willful act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in Mississippi, making it unlawful under Miss. Code § 75-24-1, *et seq.*

1218. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresentation of the source, sponsorship, approval, or certification of goods or services; (b) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have; (c) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; (d) advertising goods or services with intent not to sell them as advertised; and (d) engaging in fraudulent and

deceptive conduct that creates a likelihood of confusion and misunderstanding. Miss. Code § 75-24-5.

1219. Philips' conduct was unfair, fraudulent, and/or deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Mississippi Plaintiffs. Ordinary consumers, including Mississippi Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Mississippi Plaintiffs', as well as Mississippi Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1220. Philips owed Mississippi Plaintiffs and Mississippi Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Mississippi Plaintiffs or Mississippi Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1221. Mississippi Plaintiffs and members of the Mississippi Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1222. Philips' conduct actually and proximately caused loss of money or property to Mississippi Plaintiffs (as set forth above) and members of the Mississippi Subclass. Absent

Philips' unfair, deceptive, and/or fraudulent conduct, Mississippi Plaintiffs and Mississippi Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payments for the Recalled Devices. Philips' omissions induced Mississippi Plaintiffs and Mississippi Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Mississippi Plaintiffs and Mississippi Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing for the Recalled Devices) that resulted in the damages

1223. Accordingly, pursuant to Miss. Code § 75-24-1, *et seq.*, Mississippi Plaintiffs and Mississippi Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Mississippi Plaintiffs and Mississippi Subclass members are entitled to all available statutory, exemplary, treble, and/or punitive damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

1224. To the extent that any pre-suit notice was purportedly required, Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required

pre-suit notification requirements and invited Philips to engage in the alternative dispute resolution process with the Mississippi Attorney General. These letters put Philips on notice of the demands of the Mississippi Plaintiffs and Mississippi Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Mississippi Plaintiffs and Mississippi Subclass for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 45 – VIOLATIONS OF MISSOURI MERCHANDISING PRACTICES ACT**

**Mo. Rev. Stat. § 407.010, *et seq.***

**On Behalf of the Missouri Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1225. Plaintiffs Brengle and Young (“Missouri Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1226. Missouri Plaintiffs bring this cause of action individually and on behalf of the members of the Missouri Subclass.

1227. This claim is brought against the Philips Defendants.

1228. The Missouri Merchandising Practices Act was created to protect Missouri consumers from unlawful practices outlined in the statute.

1229. Missouri Plaintiffs and Missouri Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1230. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Missouri. In addition, Philips, among other things, sold the Recalled Devices in Missouri, shipped Recalled Devices to Missouri, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Missouri.

1231. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1232. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1233. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in Missouri, making it unlawful under Mo. Rev. Stat. § 407.020.

1234. Philips' conduct was fraudulent, deceptive, unconscionable and/or unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Missouri Plaintiffs. Ordinary consumers, including Missouri Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation



and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Missouri Plaintiffs', as well as Missouri Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1235. Philips owed Missouri Plaintiffs and Missouri Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Missouri Plaintiffs or Missouri Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1236. Missouri Plaintiffs and members of the Missouri Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1237. Philips' conduct actually and proximately caused loss of money or property to Missouri Plaintiffs (as set forth above) and members of the Missouri Subclass. Absent Philips' unfair, deceptive, unfair and/or unconscionable conduct, Missouri Plaintiffs and Missouri Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Missouri Plaintiffs and Missouri Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Missouri Plaintiffs and Missouri Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful

conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing for the Recalled Devices) that resulted in the damages.

1238. Accordingly, pursuant to Mo. Rev. Stat. § 407.025, Missouri Plaintiffs and Missouri Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Missouri Plaintiffs and Missouri Subclass members are entitled to all available statutory, exemplary, and/or treble damages and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 46 – VIOLATIONS OF MONTANA UNFAIR TRADE PRACTICES AND  
CONSUMER PROTECTION ACT**

**Mont. Code § 30-14-101, *et seq.***

**On Behalf of the Montana Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1239. Plaintiff David ("Montana Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1240. Montana Plaintiff brings this cause of action individually and on behalf of the members of the Montana Subclass.

1241. This claim is brought against the Philips Defendants.

1242. The Montana Unfair Trade Practices and Consumer Protection Act was created to protect Montana consumers from deceptive and unfair business practices.

1243. Montana Plaintiff and Montana Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1244. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Montana. In addition, Philips, among other things, sold the Recalled Devices in Montana, shipped Recalled Devices to Montana, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Montana.

1245. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1246. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive because the Recalled Devices were sold as breathing assistance devices.

1247. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled

Devices, in trade or commerce in Montana, making it unlawful under Mont. Code § 30-14-101, *et seq.*

1248. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; and (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not.

1249. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Montana Plaintiff. Ordinary consumers, including Montana Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Montana Plaintiff's and Montana Subclass members' decisions to purchase, lease, or reimburse payment for the Recalled Devices.

1250. Philips owed Montana Plaintiff and Montana Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Montana Plaintiff or Montana Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1251. Montana Plaintiff and members of the Montana Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1252. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Montana Plaintiff and Montana Subclass members. Absent Philips' unfair, deceptive and/or fraudulent conduct, Montana Plaintiff and Montana Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Montana Plaintiff and Montana Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Montana Plaintiff and Montana Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1253. Accordingly, pursuant to Mont. Code § 30-14-101, *et seq.*, Montana Plaintiff and Montana Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Montana Plaintiff and Montana Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs

of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 47 – VIOLATIONS OF NEBRASKA CONSUMER PROTECTION ACT**

**Neb. Rev. Stat. § 59-1601, *et seq.***

**On Behalf of the Nebraska Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1254. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1255. Plaintiffs bring this cause of action individually and on behalf of the members of the Nebraska Subclass.

1256. This claim is brought against the Philips Defendants.

1257. The Nebraska Consumer Protection Act was created to protect Nebraska consumers from deceptive and unfair business practices that restrain trade and commerce in Nebraska.

1258. Plaintiffs and Nebraska Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1259. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Nebraska. In addition, Philips, among other things, sold the Recalled Devices in Nebraska, shipped Recalled Devices to Nebraska, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Nebraska.

1260. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips

intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1261. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive because the Recalled Devices were sold as breathing assistance devices.

1262. Philips' conduct constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in restraint of trade or commerce in Nebraska, which affects the public interest, making it unlawful under Neb. Rev. Stat. § 59-1601, *et seq.*

1263. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Plaintiffs. Ordinary consumers, including Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Plaintiffs' and Nebraska Subclass members' decisions to purchase, lease, or reimburse payment for the Recalled Devices.

1264. Philips owed Plaintiffs and Nebraska Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along

with PolyTech and potentially other unnamed parties who are not Plaintiffs or Nebraska Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1265. Plaintiffs and members of the Nebraska Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these representations and/or omissions, in part, because they are representations and/or omissions that impact seriously on a consumer's health and well-being.

1266. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Plaintiffs and Nebraska Subclass members. Absent Philips' unfair, deceptive and/or fraudulent conduct, Plaintiffs and Nebraska Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Plaintiffs and Nebraska Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Plaintiffs and Nebraska Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1267. Accordingly, pursuant to Neb. Rev. Stat. § 59-1601, *et seq.*, Plaintiffs and Nebraska Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their



prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Nebraska Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 48 – VIOLATIONS OF NEBRASKA UNIFORM DECEPTIVE TRADE  
PRACTICES ACT**

**Neb. Rev. Stat. § 87-301, *et seq.***

**On Behalf of the Nebraska Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1268. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1269. Plaintiffs bring this cause of action individually and on behalf of the members of the Nebraska Subclass.

1270. This claim is brought against the Philips Defendants.

1271. The Nebraska Uniform Deceptive Trade Practices Act was created to protect Nebraska consumers from deceptive and unfair business practices.

1272. Plaintiffs and Nebraska Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1273. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Nebraska. In addition, Philips, among other things, sold the Recalled Devices in Nebraska, shipped Recalled Devices to Nebraska, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Nebraska.

1274. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1275. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive because the Recalled Devices were sold as breathing assistance devices.

1276. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in Nebraska, making it unlawful under Neb. Rev. Stat. § 87-301, *et seq.*

1277. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that

goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1278. Philips' conduct was fraudulent, deceptive, and unconscionable because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Plaintiffs. Ordinary consumers, including Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Plaintiffs' and Nebraska Subclass members' decisions to purchase, lease, or reimburse payment for the Recalled Devices.

1279. Philips owed Plaintiffs and Nebraska Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Plaintiffs or Nebraska Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1280. Plaintiffs and members of the Nebraska Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1281. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Plaintiffs and Nebraska Subclass members. Absent Philips' unfair, deceptive,

fraudulent, and/or unconscionable conduct, Plaintiffs and Nebraska Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Plaintiffs and Nebraska Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Plaintiffs and Nebraska Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages

1282. Accordingly, pursuant to Neb. Rev. Stat. § 87-301, *et seq.*, Plaintiffs and Nebraska Subclass members are entitled any and all equitable relief necessary or proper to protect them from Philips' unlawful conduct.

**COUNT 49 – VIOLATIONS OF NEVADA DECEPTIVE TRADE PRACTICES ACT**

**Nev. Rev. Stat. § 598.0999, *et seq.***

**On Behalf of the Nevada Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1283. Plaintiff Lemus ("Nevada Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1284. Nevada Plaintiff brings this cause of action individually and on behalf of the members of the Nevada Subclass.

1285. This claim is brought against the Philips Defendants.

1286. The Nevada Deceptive Trade Practices Act was created to protect Nevada consumers from deceptive and unfair business practices.

1287. Nevada Plaintiff and Nevada Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1288. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Nevada. In addition, Philips, among other things, sold the Recalled Devices in Nevada, shipped Recalled Devices to Nevada, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Nevada.

1289. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed a serious health risk to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1290. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive because the Recalled Devices were sold as breathing assistance devices.

1291. Philips' conduct described herein constitutes the knowing and willing act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in Nevada, making it unlawful under Nev. Rev. Stat. § 598.0999, *et seq.*

1292. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Nevada Plaintiff. Ordinary consumers, including Nevada Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Nevada Plaintiff's and Nevada Subclass members' decisions to purchase, lease, or reimburse payment for the Recalled Devices.

1293. Philips owed Nevada Plaintiff and Nevada Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Nevada Plaintiff or members of the Nevada Subclass) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1294. Nevada Plaintiff and Nevada Subclass members justifiably relied on the material misstatements and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these statements and/or omissions, in part, because they are statements and/or omissions that impact seriously on a consumer's health and well-being.

1295. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Nevada Plaintiff and Nevada Subclass members. Absent Philips' unfair, deceptive, fraudulent, and/or unconscionable conduct, Nevada Plaintiff and Nevada Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment

for the Recalled Devices. Philips' omissions induced Nevada Plaintiff and Nevada Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Nevada Plaintiff and Nevada Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages

1296. Accordingly, pursuant to Nev. Rev. Stat. § 598.0999, *et seq.*, Nevada Plaintiff and Nevada Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Nevada Plaintiff and Nevada Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 50 – VIOLATIONS OF NEW HAMPSHIRE CONSUMER PROTECTION ACT**

**N.H. Rev. Stat. § 358-A:1, *et seq.***

**On Behalf of the New Hampshire Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1297. Plaintiffs Lizotte, Malone, and Vlahos ("New Hampshire Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1298. New Hampshire Plaintiffs bring this cause of action individually and on behalf of the members of the New Hampshire Subclass.

1299. This claim is brought against the Philips Defendants.

1300. The New Hampshire Consumer Protection Act was created to protect New Hampshire consumers from deceptive, unconscionable and unfair business practices.

1301. New Hampshire Plaintiffs and New Hampshire Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1302. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in New Hampshire. In addition, Philips, among other things, sold the Recalled Devices in New Hampshire, shipped Recalled Devices to New Hampshire, and otherwise engaged in trade or commerce, and or conducted business, related to the Recalled Devices in New Hampshire.

1303. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1304. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.



1305. Philips' conduct constitutes the knowing and reckless act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the advertisement and sale of merchandise, the Recalled Devices, in trade or commerce in New Hampshire, making it unlawful under N.H. Rev. Stat. § 358-A:1, *et seq.*

1306. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) advertising the Recalled Devices with intent not to sell them as advertised.

1307. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including New Hampshire Plaintiffs. Reasonable consumers, including New Hampshire Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in New Hampshire Plaintiffs', as well as New Hampshire Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1308. Philips owed New Hampshire Plaintiffs and New Hampshire Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not

New Hampshire Plaintiffs or New Hampshire Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1309. New Hampshire Plaintiffs, and members of the New Hampshire Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1310. Philips' conduct actually and proximately caused an ascertainable loss of money or property to New Hampshire Plaintiffs (as set forth above) and members of the New Hampshire Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, New Hampshire Plaintiffs and New Hampshire Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced New Hampshire Plaintiffs and New Hampshire Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. New Hampshire Plaintiffs and New Hampshire Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1311. Accordingly, pursuant to under N.H. Rev. Stat. § 358-A:1, *et seq.*, given that Philips' conduct was done willfully and knowingly, New Hampshire Plaintiffs and New Hampshire Subclass members are entitled to recover threefold their actual damages or statutory

damages in the amount of \$1,000, whichever is greater. Actual damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental or consequential damages. New Hampshire Plaintiffs and New Hampshire Subclass members are also entitled to injunctive relief; and all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary; and all such other relief as the Court deems proper.

**COUNT 51 – VIOLATIONS OF NEW JERSEY CONSUMER FRAUD ACT**

**N.J. Stat. Ann. § 56:8-1, *et seq.***

**On Behalf of the New Jersey Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1312. Plaintiffs Dennis, Gold, Ryan, Taylor, and Ohio Carpenters ("New Jersey Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1313. New Jersey Plaintiffs bring this action individually and on behalf of the members of the New Jersey Subclass.

1314. This claim is brought against the Philips Defendants.

1315. The New Jersey Consumer Fraud Act was created to protect New Jersey consumers from fraudulent business practices.

1316. New Jersey Plaintiffs and New Jersey Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1317. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in New Jersey. In addition, Philips, among other things, sold the Recalled Devices in New Jersey, shipped Recalled Devices to New Jersey, and otherwise

engaged in trade or commerce, or conducted business, related to the Recalled Devices in New Jersey.

1318. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1319. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1320. Philips knowingly engaged in deceptive, unconscionable, unlawful, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation, in violation of N.J. Stat. Ann. § 56:8-2.

1321. Philips' conduct was fraudulent, deceptive, unconscionable and unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or

tendency to deceive and, in fact, did deceive, reasonable consumers, including New Jersey Plaintiffs. Reasonable consumers, including New Jersey Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in New Jersey Plaintiffs', as well as New Jersey Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1322. Philips owed New Jersey Plaintiffs and New Jersey Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not New Jersey Plaintiffs or New Jersey Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1323. New Jersey Plaintiffs, and members of the New Jersey Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1324. Philips' conduct actually and proximately caused an ascertainable loss of money or property to New Jersey Plaintiffs (as set forth above) and members of the New Jersey Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, New Jersey Plaintiffs and New Jersey Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced New Jersey

Plaintiffs and New Jersey Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. New Jersey Plaintiffs and New Jersey Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1325. Accordingly, pursuant to N.J. Stat. Ann. § 56:8-1, *et seq.*, New Jersey Plaintiffs and New Jersey Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, New Jersey Plaintiffs and New Jersey Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 52 – VIOLATIONS OF NEW MEXICO UNFAIR PRACTICES ACT**

**N.M. Stat. Ann. § 57-12-1, *et seq.***

**On Behalf of the New Mexico Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1326. Plaintiff Rodgers ("New Mexico Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1327. New Mexico Plaintiff brings this action individually and on behalf of the members of the New Mexico Subclass.

1328. This claim is brought against the Philips Defendants.

1329. The New Mexico Unfair Trade Practices Act was created to protect New Mexico consumers from unfair, deceptive and unconscionable trade practices.

1330. New Mexico Plaintiff and New Mexico Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1331. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in New Mexico. In addition, Philips, among other things, sold the Recalled Devices in New Mexico, shipped Recalled Devices to New Mexico, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in New Mexico.

1332. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed significant risks of substantial physical injury to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1333. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was

particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1334. Philips has knowingly engaged in deceptive, unconscionable, unlawful, unfair, false, fraudulent, and misleading commercial practices, including misleading omissions of material fact, in connection with the oral and written marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation, in violation of N.M. Stat. Ann. § 57-12-1, *et seq.*

1335. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable and unfair trade practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, benefits or quantities, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) using exaggeration or ambiguity in failing to state a material fact to deceive; and (d) receiving a value that was grossly disproportionate to the price paid for the Recalled Devices.

1336. Philips' conduct was unfair, fraudulent, deceptive and unconscionable because the omissions had the capacity or tendency to deceive and, in fact, did deceive, reasonable consumers, including New Mexico Plaintiff. Reasonable consumers, including New Mexico Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in New Mexico Plaintiff's, as well as New Mexico Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.



1337. Philips owed New Mexico Plaintiff and New Mexico Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not New Mexico Plaintiff or New Mexico Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1338. New Mexico Plaintiff and members of the New Mexico Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1339. Philips' conduct actually and proximately caused an ascertainable loss of money or property to New Mexico Plaintiff (as set forth above) and members of the New Mexico Subclass. Absent Philips' unfair, fraudulent, deceptive, and unconscionable conduct, New Mexico Plaintiff and New Mexico Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced New Mexico Plaintiff and New Mexico Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. New Mexico Plaintiff and New Mexico Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages

1340. Accordingly, pursuant to the aforementioned statutes, New Mexico Plaintiff and New Mexico Subclass members are entitled to injunctive relief and recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, New Mexico Plaintiff and New Mexico Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 53 – VIOLATIONS OF NEW YORK DECEPTIVE TRADE PRACTICES ACT  
AND FALSE ADVERTISING**

**N.Y. Gen. Bus. Law § 349; § 350**

**On Behalf of the New York Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1341. Plaintiffs Bossey, Ginsberg, Gold, and MSP ("New York Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1342. New York Plaintiffs bring this action individually and on behalf of the members of the New York Subclass.

1343. This claim is brought against the Philips Defendants.

1344. The N.Y. Gen. Bus. Laws were created to protect New York consumers from fraudulent business practices and false advertising.

1345. New York Plaintiffs and New York Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1346. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in New York. In addition, Philips, among other things, sold the Recalled Devices in New York, shipped Recalled Devices to New York, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in New York.

1347. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1348. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1349. Philips unfairly engaged in deceptive, unconscionable, unlawful, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation and off-gassing, in violation of N.Y. Gen. Bus. Law §§ 349, 350.

1350. Philips' conduct constituted, among other things, the following prohibited deceptive, misleading, and/or false advertising practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1351. Philips' conduct was deceptive, misleading, and false advertising because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including New York Plaintiffs. Ordinary consumers, including New York Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in New York Plaintiffs', as well as other New York Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1352. Philips owed New York Plaintiffs and New York Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not New York Plaintiffs or New York Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1353. New York Plaintiffs, and members of the New York Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1354. Philips' conduct actually and proximately caused loss of money or property to New York Plaintiffs (as set forth above) and members of the New York Subclass. Absent Philips' deceptive, misleading, and/or fraudulent conduct, New York Plaintiffs and New York Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced New York Plaintiffs and New York Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. New York Plaintiffs and New York Subclass members acted as reasonable consumers would have acted under the circumstances and entered into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1355. Accordingly, pursuant to N.Y. Gen. Bus. Law § 349 and § 350, New York Plaintiffs and New York Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, New York Plaintiffs and New York Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and attorneys' fees based on the amount of

time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 54 – VIOLATIONS OF NORTH CAROLINA UNFAIR AND DECEPTIVE  
TRADE PRACTICES ACT**

**N.C. Gen. Stat. § 75-1, *et seq.***

**On Behalf of the North Carolina Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1356. Plaintiffs Bartalo and Margoles (“North Carolina Plaintiffs”) hereby reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1357. North Carolina Plaintiffs bring this action individually and on behalf of the members of the North Carolina Subclass.

1358. This claim is brought against the Philips Defendants.

1359. The North Carolina Unfair and Deceptive Trade Practices Act was created to protect North Carolina consumers from unfair or deceptive business practices.

1360. North Carolina Plaintiffs and North Carolina Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1361. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in North Carolina. In addition, Philips, among other things, sold the Recalled Devices in North Carolina, shipped Recalled Devices to North Carolina, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in North Carolina.

1362. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as

they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1363. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1364. Philips engaged in immoral, unethical, oppressive, unscrupulous, substantially injurious and misleading commercial practices, with the intent to deceive the consumer in connection with the marketing, promotion and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation and off-gassing.

1365. Philips' conduct constituted, among other things, the following prohibited deceptive, misleading, and/or false practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1366. Philips' conduct was deceptive, misleading, and false advertising because the omissions created a likelihood of confusion and misunderstanding and had the capacity or

tendency to deceive and, in fact, did deceive, ordinary consumers, including North Carolina Plaintiffs. Ordinary consumers, including North Carolina Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in North Carolina Plaintiffs', as well as other North Carolina Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1367. Philips owed North Carolina Plaintiffs and North Carolina Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not North Carolina Plaintiffs or North Carolina Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1368. North Carolina Plaintiffs, and members of the North Carolina Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1369. Philips' conduct actually and proximately caused loss of money or property North Carolina Plaintiffs (as set forth above) and members of the North Carolina Subclass. Absent Philips' deceptive, misleading, and/or fraudulent conduct, North Carolina Plaintiffs and North Carolina Subclass members would have behaved differently and would not have purchased,



leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced North Carolina Plaintiffs and North Carolina Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. North Carolina Plaintiffs and North Carolina Subclass members acted as reasonable consumers would have acted under the circumstances and entered into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1370. Accordingly, pursuant to N.C. Gen. Stat. § 75-1, *et seq.*, North Carolina Plaintiffs and North Carolina Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), and/or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, North Carolina Plaintiffs and North Carolina Subclass members are entitled to recover statutory, exemplary, treble, and/or punitive damages, together with interest, cost of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 55 – VIOLATIONS OF NORTH DAKOTA UNLAWFUL SALES OR  
ADVERTISING PRACTICES ACT**

**N.D. Cent. Code § 51-15-01, *et seq.***

**On Behalf of the North Dakota Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1371. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1372. Plaintiffs bring this action individually and on behalf of the members of the North Dakota Subclass.

1373. This claim is brought against the Philips Defendants.

1374. The North Dakota Unlawful Sales or Advertising Act was created to protect North Dakota consumers from fraudulent business practices.

1375. North Dakota Plaintiffs and North Dakota Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1376. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in North Dakota. In addition, Philips, among other things, sold the Recalled Devices in North Dakota, shipped Recalled Devices to North Dakota, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in North Dakota.

1377. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1378. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing

of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1379. Philips intentionally and knowingly engaged in deceptive acts or practices, fraud, false pretense, false promise and misleading and unconscionable commercial practices, including misleading omissions of material fact, in connection with the advertisement, marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

1380. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1381. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including North Dakota Plaintiffs. Ordinary consumers, including North Dakota Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in the North Dakota Plaintiffs', as well as North Dakota Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1382. Philips owed North Dakota Plaintiffs and North Dakota Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not North Dakota Plaintiffs or North Dakota Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1383. North Dakota Plaintiffs and members of the North Dakota Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1384. Philips' conduct actually and proximately caused an ascertainable loss of money or property to North Dakota Plaintiffs (as set forth above) and members of the North Dakota Subclass. Absent Philips' unfair, deceptive, unconscionable, and/or fraudulent conduct, North Dakota Plaintiffs and North Dakota Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced North Dakota Plaintiffs and North Dakota Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1385. Accordingly, pursuant to the aforementioned statutes, North Dakota Plaintiffs and North Dakota Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as

represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, North Dakota Plaintiffs and North Dakota Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 56 – VIOLATIONS OF OHIO CONSUMER SALES PRACTICES ACT**

**Ohio Rev. Code § 1345.01, *et seq.***

**On Behalf of the Ohio Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1386. Plaintiffs Flick, Fultz, Giordano, Hock, Stefanini, Ward, Ohio Carpenters, and MSP ("Ohio Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1387. Ohio Plaintiffs bring this action individually and on behalf of the members of the Ohio Subclass.

1388. This claim is brought against the Philips Defendants.

1389. The Ohio Consumer Sales Practices Act was created to protect Ohio consumers from fraudulent or deceptive business practices.

1390. Ohio Plaintiffs and Ohio Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1391. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Ohio. In addition, Philips, among other things, sold the Recalled Devices in Ohio, shipped Recalled Devices to Ohio, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Ohio.

1392. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1393. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1394. Philips intentionally engaged in deceptive and unfair acts or practices, false promises and misleading and unconscionable commercial practices, including misleading omissions of material fact, in connection with the advertisement, marketing, promotion and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation.

1395. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that

goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1396. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Ohio Plaintiffs. Ordinary consumers, including Ohio Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Ohio Plaintiffs', as well as Ohio Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1397. Philips owed Ohio Plaintiffs and Ohio Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Ohio Plaintiffs or Ohio Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1398. Ohio Plaintiffs and members of the Ohio Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1399. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the Ohio Plaintiffs (as set forth above) and members of the Ohio Subclass. Absent

Philips' unfair, deceptive, and/or fraudulent conduct, Ohio Plaintiffs and Ohio Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the Ohio Plaintiffs and Ohio Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1400. Accordingly, pursuant to the aforementioned statutes, Ohio Plaintiffs and Ohio Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, the Ohio Plaintiffs and Ohio Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 57 – VIOLATIONS OF OKLAHOMA CONSUMER PROTECTION ACT**

**15 Okla. Stat. Ann. § 751, *et seq.***

**On Behalf of the Oklahoma Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1401. Plaintiffs Mcelyea and Ohio Carpenters ("Oklahoma Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1402. Oklahoma Plaintiffs bring this action individually and on behalf of the members of the Oklahoma Subclass.

1403. This claim is brought against the Philips Defendants.



1404. The Oklahoma Consumer Protection Act was created to protect Oklahoma consumers from unfair methods of competition and unfair or deceptive business practices.

1405. Oklahoma Plaintiffs and the Oklahoma Subclass purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1406. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Oklahoma. In addition, Philips, among other things, sold the Recalled Devices in Oklahoma, shipped Recalled Devices to Oklahoma, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Oklahoma.

1407. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1408. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1409. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1410. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Oklahoma Plaintiffs. Ordinary consumers, including Oklahoma Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Oklahoma Plaintiffs', as well as Oklahoma Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1411. Philips owed Oklahoma Plaintiffs and Oklahoma Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Oklahoma Plaintiffs or Oklahoma Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1412. Oklahoma Plaintiffs and members of the Oklahoma Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would

have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1413. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Oklahoma Plaintiffs (as set forth above) and members of the Oklahoma Subclass. Absent Philips' unfair, deceptive, and/or fraudulent conduct, Oklahoma Plaintiffs and Oklahoma Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Oklahoma Plaintiffs and Oklahoma Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1414. Accordingly, pursuant to the aforementioned statutes, Oklahoma Plaintiffs and Oklahoma Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Oklahoma Plaintiffs and Oklahoma Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 58 – VIOLATIONS OF OREGON UNLAWFUL TRADE PRACTICES ACT**

**Or. Rev. Stat. § 646.605, et seq.**

**On Behalf of the Oregon Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1415. Plaintiffs Julie Barrett, Peter Barrett, and Nielson ("Oregon Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1416. Oregon Plaintiffs bring this action individually and on behalf of the members of the Oregon Subclass.

1417. This claim is brought against the Philips Defendants.

1418. The Oregon Unlawful Trade Practices Act was created to protect Oregon consumers from fraudulent or deceptive business practices.

1419. Oregon Plaintiffs and Oregon Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1420. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Oregon. In addition, Philips, among other things, sold the Recalled Devices in Oregon, shipped Recalled Devices to Oregon, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Oregon.

1421. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1422. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was

particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1423. Philips willfully, knowingly, and recklessly engaged in deceptive, unfair, false, fraudulent and misleading commercial practices, including misleading representation, or omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation, in violation of Or. Rev. Stat. § 646.607.

1424. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, unconscionable, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1425. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Oregon Plaintiffs. Ordinary consumers, including Oregon Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Oregon Plaintiffs', as well as other Oregon Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1426. Philips owed Oregon Plaintiffs and Oregon Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips

(along with PolyTech and potentially other unnamed parties who are not Oregon Plaintiffs or Oregon Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1427. Oregon Plaintiffs, and members of the Oregon Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1428. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the Oregon Plaintiffs (as set forth above) and members of the Oregon Subclass. Absent Philips' unfair, deceptive, and/or fraudulent conduct, Oregon Plaintiffs and Oregon Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the Oregon Plaintiffs and Oregon Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Oregon Plaintiffs and Oregon Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1429. Accordingly, pursuant to Or. Rev. Stat. § 646.605, *et seq.*, Oregon Plaintiffs and Oregon Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their

prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Oregon Plaintiffs and Oregon Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 59 – VIOLATIONS OF PENNSYLVANIA UNFAIR TRADE PRACTICES AND  
CONSUMER PROTECTION LAW**

**73 Pa. Stat. Ann. § 201-1, *et seq.***

**On Behalf of the Pennsylvania Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1430. Plaintiffs Masington, Sweeney, and Ohio Carpenters ("Pennsylvania Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1431. Pennsylvania Plaintiffs bring this action individually and on behalf of the members of the Pennsylvania Subclass.

1432. This claim is brought against the Philips Defendants.

1433. The Pennsylvania Unfair Trade Practices and Consumer Protection Law was created to protect Pennsylvania consumers from fraudulent or deceptive business practices.

1434. Pennsylvania Plaintiffs and Pennsylvania Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1435. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Pennsylvania. In addition, Philips, among other things, sold the Recalled Devices in Pennsylvania, shipped Recalled Devices to Pennsylvania, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Pennsylvania.

1436. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1437. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1438. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1439. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Pennsylvania Plaintiffs. Ordinary consumers,



including Pennsylvania Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Pennsylvania Plaintiffs', as well as other Pennsylvania Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1440. Philips owed Pennsylvania Plaintiffs and Pennsylvania Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Pennsylvania Plaintiffs or Pennsylvania Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1441. Pennsylvania Plaintiffs, and members of the Pennsylvania Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1442. Philips' conduct actually and proximately caused loss of money or property to Pennsylvania Plaintiffs (as set forth above) and members of the Pennsylvania Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Pennsylvania Plaintiffs and Pennsylvania Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Pennsylvania Plaintiffs and Pennsylvania Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Pennsylvania Plaintiffs and

Pennsylvania Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1443. Accordingly, pursuant to the 73 Pa. Stat. Ann. § 201-1, *et seq.*, Pennsylvania Plaintiffs and Pennsylvania Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Pennsylvania Plaintiffs and Pennsylvania Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 60 – VIOLATIONS OF RHODE ISLAND UNFAIR TRADE PRACTICE AND  
CONSUMER PROTECTION ACT**

**R.I. Gen. Laws § 6-13.1-1, *et seq.***

**On Behalf of the Rhode Island Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1444. Plaintiffs Lamontagne, Weiner, and MSP ("Rhode Island Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1445. Rhode Island Plaintiffs bring this action individually and on behalf of the members of the Rhode Island Subclass.

1446. This claim is brought against the Philips Defendants.

1447. The Rhode Island Unfair Trade Practice and Consumer Protection Act was created to protect Rhode Island consumers from unfair and deceptive business practices.

1448. Rhode Island Plaintiffs and Rhode Island Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1449. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Rhode Island. In addition, Philips, among other things, sold the Recalled Devices in Rhode Island, shipped Recalled Devices to Rhode Island, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Rhode Island.

1450. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1451. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1452. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1453. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Rhode Island Plaintiffs. Ordinary consumers, including Rhode Island Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Rhode Island Plaintiffs', as well as Rhode Island Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1454. Philips owed Rhode Island Plaintiffs and Rhode Island Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Rhode Island Plaintiffs or Rhode Island Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1455. Rhode Island Plaintiffs and members of the Rhode Island Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers

would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1456. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the Rhode Island Plaintiffs (as set forth above) and members of the Rhode Island Subclass. Absent Philips' unfair, deceptive, and/or fraudulent conduct, Rhode Island Plaintiffs and Rhode Island Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the Rhode Island Plaintiffs and Rhode Island Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1457. Accordingly, pursuant to the aforementioned statutes, Rhode Island Plaintiffs and Rhode Island Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Rhode Island Plaintiffs and Rhode Island Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 61 – VIOLATIONS OF SOUTH CAROLINA UNFAIR TRADE PRACTICES  
ACT**

**S.C. Code Ann. § 39-5-10, *et seq.***

**On Behalf of the South Carolina Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1458. Plaintiffs William Anderson and Ohio Carpenters (“South Carolina Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1459. South Carolina Plaintiffs bring this action individually and on behalf of the members of the South Carolina Subclass.

1460. This claim is brought against the Philips Defendants.

1461. The South Carolina Unfair Trade Practices Act (“SCUTPA”) was created to protect South Carolina consumers from fraudulent or deceptive business practices.

1462. South Carolina Plaintiffs, South Carolina Subclass members, and Philips are persons under the SCUTPA.

1463. South Carolina Plaintiffs and South Carolina Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1464. Philips engaged in trade or commerce related to the Recalled Devices directly affecting the people of South Carolina. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in South Carolina. In addition, Philips, among other things, sold the Recalled Devices in South Carolina, shipped Recalled Devices to South Carolina, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in South Carolina.

1465. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in

that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1466. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1467. Philips knowingly engaged in unlawful, unfair, deceptive, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of the Recalled Devices, misrepresenting their safety and failing to disclose the dangers caused by the PE-PUR foam degradation, which are unlawful under, among other things, S.C. Code Ann. § 39-5-20.

1468. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1469. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including South Carolina Plaintiffs. Ordinary consumers, including South Carolina Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in South Carolina Plaintiffs', as well as South Carolina Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1470. Philips owed South Carolina Plaintiffs and Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not South Carolina Plaintiffs or South Carolina Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1471. South Carolina Plaintiffs and members of the South Carolina Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1472. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the South Carolina Plaintiffs (as set forth above) and members of the South Carolina Subclass. Absent Defendants' unfair, deceptive, and/or fraudulent conduct, South Carolina Plaintiffs and South Carolina Subclass members would have behaved differently and



would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the South Carolina Plaintiffs and South Carolina Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1473. Accordingly, pursuant to S.C. Code Ann. § 39-5-10, *et seq.*, South Carolina Plaintiffs and South Carolina Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, South Carolina Plaintiffs and South Carolina Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 62 – VIOLATIONS OF SOUTH DAKOTA DECEPTIVE TRADE PRACTICES  
AND CONSUMER PROTECTION LAW**

**S.D. Codified Laws § 37-24-1, *et seq.***

**On Behalf of the South Dakota Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1474. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1475. Plaintiffs bring this action individually and on behalf of the members of the South Dakota Subclass.

1476. This claim is brought against the Philips Defendants.

1477. The South Dakota Deceptive Trade Practices and Consumer Protection Act was created to protect South Dakota consumers from fraudulent or deceptive business practices.

1478. Plaintiffs, South Dakota Subclass members, and Philips are persons under South Dakota's Deceptive Trade Practices and Consumer Protection Act.

1479. Plaintiffs and South Dakota Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1480. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in South Dakota. In addition, Philips, among other things, sold the Recalled Devices in South Dakota, shipped Recalled Devices to South Dakota, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in South Dakota.

1481. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1482. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was

particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1483. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts in connection with the sale and advertisement of merchandise, the Recalled Devices, in trade or commerce in South Dakota, making it unlawful under S.D. Codified Laws § 37-24-6.

1484. Philips' conduct was fraudulent and deceptive because, among other things, the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Plaintiffs. Ordinary consumers, including Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Plaintiffs', as well as other South Dakota Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1485. Philips owed Plaintiffs and South Dakota Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Plaintiffs or South Dakota Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1486. Plaintiffs, and members of the South Dakota Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1487. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the Plaintiffs (as set forth above) and members of the South Dakota Subclass. Absent Philips' unfair, deceptive, and/or fraudulent conduct, Plaintiffs and South Dakota Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the Plaintiffs and South Dakota Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Plaintiffs and South Dakota Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1488. Accordingly, pursuant to the S.D. Codified Laws § 37-24-31, Plaintiffs and South Dakota Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and South Dakota Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and

attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 63 – VIOLATIONS OF TENNESSEE CONSUMER PROTECTION ACT**

**Tenn. Code Ann. § 47-18-101, *et seq.***

**On Behalf of the Tennessee Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1489. Plaintiffs Cote, Craig, and Ohio Carpenters ("Tennessee Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1490. Tennessee Plaintiffs bring this cause of action individually and on behalf of the members of the Tennessee Subclass.

1491. This claim is brought against the Philips Defendants.

1492. The Tennessee Consumer Protection Act ("TCPA") was created to protect Tennessee consumers from fraudulent or deceptive business practices.

1493. Tennessee Plaintiffs, Tennessee Subclass members, and Philips are persons under the TCPA.

1494. Tennessee Plaintiffs and Tennessee Subclass members are natural persons who purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1495. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Tennessee. In addition, Philips, among other things, sold the Recalled Devices in Tennessee, shipped Recalled Devices to Tennessee, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Tennessee.

1496. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as

they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1497. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1498. Philips' conduct constitutes "[u]nfair or deceptive acts or practices affecting the conduct of any trade or commerce" in Tennessee, making it unlawful under Tenn. Code Ann. § 47-18-104(a).

1499. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1500. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Tennessee Plaintiffs. Ordinary consumers, including Tennessee Plaintiffs, would have found it material to their purchasing decisions that

the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Tennessee Plaintiffs', as well as Tennessee Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1501. Philips owed Tennessee Plaintiffs and Tennessee Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Tennessee Plaintiffs or Tennessee Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1502. Tennessee Plaintiffs and members of the Tennessee Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1503. Philips' conduct actually and proximately caused an ascertainable loss of money or property to the Tennessee Plaintiffs (as set forth above) and members of the Tennessee Subclass. Absent Defendants' unfair, deceptive, and/or fraudulent conduct, Tennessee Plaintiffs and Tennessee Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced the Tennessee Plaintiffs and Tennessee Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1504. Accordingly, pursuant to the aforementioned statutes, Tennessee Plaintiffs and Tennessee Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices paid) and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Tennessee Plaintiffs and Tennessee Subclass members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

**COUNT 64 – VIOLATIONS OF TEXAS DECEPTIVE TRADE PRACTICES AND  
CONSUMER PROTECTION ACT**

**Tex. Bus. Comm. Code Ann. § 17.41, *et seq.***

**On Behalf of the Texas Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1505. Plaintiffs Claunch, Cline, Deleon, Lowney, Malone, Panzera, Rendon, Tobin, Turner, Ohio Carpenters, and MSP ("Texas Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1506. Texas Plaintiffs bring this cause of action individually and on behalf of the members of the Texas Subclass.

1507. This claim is brought against the Philips Defendants.

1508. The Texas Deceptive Trade Practices-Consumer Protection Act ("TDTPA") was created to protect Texas consumers from false, misleading, and deceptive business practices.

1509. Texas Plaintiffs, members of the Texas Subclass, and Philips are all persons under the TDTPA.



1510. Texas Plaintiffs and members of the Texas Subclass purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1511. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Texas. In addition, Philips, among other things, sold the Recalled Devices in Texas, shipped Recalled Devices to Texas, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Texas.

1512. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1513. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1514. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Tex. Bus. & Com. Code Ann. § 17.46(b), including but not limited to, misleading, misrepresenting, omitting, or supplying false information to consumers as to the

source, affiliation, certification, characteristics, ingredients, uses, benefits, quantities, standard, or condition of the Recalled Devices.

1515. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1516. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Texas Plaintiffs. Ordinary consumers, including Texas Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Texas Plaintiffs', as well as other Texas Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1517. Philips owed Texas Plaintiffs and Texas Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Texas Plaintiffs or Texas Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1518. Texas Plaintiffs and Texas Subclass members purchased the Recalled Devices for personal purposes and suffered ascertainable losses of money or property as the result of the use or employment of a method, act or practice declared unlawful by Tex. Bus. & Com. Code Ann. § 17.46(b). Texas Plaintiffs and Texas Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing the Recalled Devices) that resulted in the damages.

1519. Texas Plaintiffs and members of the Texas Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1520. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Texas Plaintiffs (as set forth above) and members of the Texas Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Texas Plaintiffs and Texas Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Texas Plaintiffs and Texas Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1521. Accordingly, pursuant to Tex. Bus. & Com. Code Ann. § 17.50(b)(1), (h), Texas Plaintiffs and Texas Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or the cost

to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Texas Plaintiffs and Texas Subclass members are entitled to recover treble damages for the willful and knowing violation of the TDTPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

1522. To the extent that any pre-suit notice was purportedly required, Philips has had notice of its violations for over a year. Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. These letters put Philips on notice of the demands of the Texas Plaintiffs and Texas Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Texas Plaintiffs and Texas Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of Texas. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 65 – VIOLATIONS OF UTAH CONSUMER SALES PRACTICES ACT**

**Utah Code Ann. § 13-11-1, *et seq.***

**On Behalf of the Utah Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1523. Plaintiff Ohio Carpenters ("Utah Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1524. Utah Plaintiff brings this cause of action individually and on behalf of the members of the Utah Subclass.

1525. This claim is brought against the Philips Defendants.

1526. The Utah Consumer Sales Practices Act (“UCSPA”) was created to protect Utah consumers from deceptive and unfair sales practices.

1527. Utah Plaintiff, Utah Subclass members, and Philips are all persons under the UCSPA.

1528. Utah Plaintiff and Utah Subclass members purchased, leased, or reimbursed payment for the Recalled Devices in consumer transactions primarily for personal purposes.

1529. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Utah. In addition, Philips, among other things, sold the Recalled Devices in Utah, shipped Recalled Devices to Utah, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Utah.

1530. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1531. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were

defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1532. Philips' conduct described herein constitutes the act, use or employment of deception, false promise, misrepresentation, unfair practice and the concealment, suppression, and omission of material facts by a supplier in connection with a consumer transaction, purchase of Recalled Devices, making it unlawful under Utah Code Ann. §§ 13-11-4(1), 13-11-5(1).

1533. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair sales practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1534. Philips' conduct was deceptive and unfair because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Utah Plaintiff. Ordinary consumers, including Utah Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Utah Plaintiff's, as well as other Utah Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1535. Philips owed Utah Plaintiff and Utah Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Utah Plaintiff or Utah Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1536. Utah Plaintiff and members of the Utah Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1537. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Utah Plaintiff (as set forth above) and members of the Utah Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Utah Plaintiff and Utah Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Utah Plaintiff and Utah Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1538. Accordingly, pursuant to Utah Code Ann. § 13-11-19(2), Utah Plaintiff and Utah Subclass members are entitled to recover either: (1) their actual damages (which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence) which are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the

cost to replace the Recalled Devices; or (2) \$2,000 each; whichever is greater. In addition, given the nature of Philips' conduct, Utah Plaintiff and Utah Subclass members are entitled to recover attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 66 – VIOLATIONS OF TRUTH IN ADVERTISING ACT (UTAH)**

**Utah Code Ann. § 13-11a-1, *et seq.***

**On Behalf of the Utah Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1539. Plaintiff Ohio Carpenters ("Utah Plaintiff") realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1540. Utah Plaintiff brings this cause of action individually and on behalf of the members of the Utah Subclass.

1541. This claim is brought against the Philips Defendants.

1542. The Truth in Advertising Act ("TIAA") was created to protect Utah consumers from deceptive, misleading, false, and unfair advertising and business practices.

1543. Utah Plaintiff, Utah Subclass members, and Philips are persons under the TIAA.

1544. Utah Plaintiff and Utah Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1545. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Utah. In addition, Philips, among other things, sold the Recalled Devices in Utah, shipped Recalled Devices to Utah, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Utah.

1546. As set forth more fully above, Philips marketed, advertised and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into



users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors and health professionals because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1547. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to Foam Toxins as a result of the degradation and off-gassing of the PE-PUR foam. These material omissions were misleading and deceptive standing alone and were particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1548. Philips' conduct described herein related to Recalled Devices constitutes deceptive, misleading, and false advertising practices and forms in the state of Utah and constitutes conduct which created a likelihood of confusion or of misunderstanding, making it unlawful under Utah Code Ann. §§ 13-11a-1, 13-11a-3(1)(t).

1549. Philips' conduct constituted, among other things, the following prohibited deceptive, misleading, and/or false advertising practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1550. Philips' conduct was deceptive, misleading, and false advertising because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Plaintiffs. Ordinary consumers, including Utah Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Utah Plaintiff's, as well as Utah Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1551. Philips owed Utah Plaintiff and Utah Subclass members a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Utah Plaintiff or Utah Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1552. Utah Plaintiff and members of the Utah Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1553. Philips' conduct actually and proximately caused an ascertainable loss of money or property to Utah Plaintiff (as set forth above) and members of the Utah Subclass. Absent Philips' deceptive, misleading, and/or fraudulent conduct, Utah Plaintiff and Utah Subclass members would have behaved differently and would not have purchased, leased, or reimbursed

payment for the Recalled Devices. Philips' omissions induced Utah Plaintiff and Utah Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done.

1554. Accordingly, pursuant to Utah Code Ann. § 13-11a-4(2)(b), Utah Plaintiff and Utah Subclass members are entitled to recover either: (1) their actual damages (which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence) which are: (a) the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or (b) the cost to replace the Recalled Devices; or (2) \$2,000 each; whichever is greater. In addition, given the nature of Philips' conduct, Utah Plaintiff and Utah Subclass members are entitled to recover attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 67 – VIOLATIONS OF VERMONT CONSUMER FRAUD ACT VIOLATIONS**

***Vt. Stat. Ann. tit. 9, § 2451, et seq.***

**On Behalf of the Vermont Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1555. Plaintiff David Martin ("Vermont Plaintiff"), realleges and incorporates by reference all preceding allegations as though fully set forth herein.

1556. Vermont Plaintiff brings this action individually and on behalf of the members of the Vermont Subclass.

1557. This claim is brought against the Philips Defendants.

1558. The Vermont Consumer Fraud Act ("VCFA") was created to protect Vermont consumers from deceptive and unfair business practices.

1559. Vermont Plaintiff and Vermont Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1560. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Vermont. In addition, Philips, among other things, sold the Recalled Devices in Vermont, shipped Recalled Devices to Vermont, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Vermont.

1561. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1562. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1563. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair, and/or deceptive acts or practices in commerce in Vermont, making it unlawful under Vt. Stat. Ann. tit. 9, § 2453(a).

1564. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Vermont Plaintiff. Ordinary consumers, including Vermont Plaintiff, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Vermont Plaintiff's, as well as other Vermont Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1565. Philips owed Vermont Plaintiff and the Vermont Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Vermont Plaintiff or Vermont Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1566. Vermont Plaintiff, and members of the Vermont Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1567. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to Vermont Plaintiff (as set forth above) and members of the Vermont Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Vermont Plaintiff and the Vermont Subclass members would have behaved differently and would not have

purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Vermont Plaintiff and Vermont Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Vermont Plaintiff and Vermont Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1568. Accordingly, pursuant to Vt. Stat. Ann. tit. 9, § 2461(b), Vermont Plaintiff and Vermont Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Vermont Plaintiff and Vermont Subclass Members are entitled to recover treble damages for the willful, wanton, and malicious violation of the VCFA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 68 – VIOLATIONS OF VIRGINIA CONSUMER PROTECTION ACT**

**Va. Code Ann. § 59.1-196, *et seq.***

**On Behalf of the Virginia Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1569. Plaintiffs Heilman, Hudson, Rodgers, Rose, and Ohio Carpenters ("Virginia Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1570. Virginia Plaintiffs bring this cause of action individually and on behalf of the members of the Virginia Subclass.

1571. This claim is brought against the Philips Defendants.

1572. The Virginia Consumer Protection Act (“VCPA”) was created to protect Virginia consumers from deceptive and unfair business practices.

1573. Virginia Plaintiffs, Virginia Subclass members, and Philips are persons under the VCPA.

1574. Virginia Plaintiffs, and Virginia Subclass members purchased the Recalled Devices in consumer transactions, *i.e.*, for personal purposes.

1575. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Virginia. In addition, Philips, among other things, sold the Recalled Devices in Virginia, shipped Recalled Devices to Virginia, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Virginia.

1576. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1577. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were

defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1578. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Va. Code Ann. § 59.1-200(A)(1)-(60) including but not limited to: misrepresentations as to a product's characteristics; misrepresentations as to a product's standard or style; advertising goods with intent not to sell as advertised; and any other deception, fraud, false pretense, false promise, or misrepresentation in connection with a consumer transaction.

1579. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Virginia Plaintiffs. Ordinary consumers, including Virginia Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Virginia Plaintiffs', as well as other Virginia Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1580. Philips owed Virginia Plaintiffs and the Virginia Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Virginia Plaintiffs or Virginia Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed



them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1581. Virginia Plaintiffs, and members of the Virginia Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1582. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to Virginia Plaintiffs (as set forth above) and members of the Virginia Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Virginia Plaintiffs and the Virginia Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Virginia Plaintiffs and Virginia Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Virginia Plaintiffs and Virginia Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1583. Accordingly, pursuant to Va. Code § 59.1-204(A), Virginia Plaintiffs and Virginia Subclass members are entitled to recover either (1) their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence, and those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase (\$0.00), or the cost to replace the Recalled Devices; or (2) \$500 each, whichever is greater. In addition, given the nature of

Philips' conduct, Virginia Plaintiffs and Virginia Subclass members are entitled to recover treble damages (or \$1,000 each, whichever is greater) for the willful and knowing violation of the VCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 69 – VIOLATIONS OF WASHINGTON CONSUMER PROTECTION ACT**

**Wash. Rev. Code § 19.86.020, *et seq.***

**On Behalf of the Washington Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1584. Plaintiffs Lopez and Peebles ("Washington Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1585. Washington Plaintiffs bring this cause of action individually and on behalf of the members of the Washington Subclass.

1586. This claim is brought against the Philips Defendants.

1587. The Washington Unfair Business Practices – Consumer Protection Act ("WCPA") was created to protect Washington consumers from deceptive and unfair business practices.

1588. Washington Plaintiffs, Washington Subclass members, and Philips are persons under the WCPA.

1589. Washington Plaintiffs and Washington Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1590. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Washington. In addition, Philips, among other things, sold the Recalled Devices in Washington, shipped Recalled Devices to Washington, and otherwise

engaged in trade or commerce, or conducted business, related to the Recalled Devices in Washington.

1591. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1592. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1593. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce in Washington, making it unlawful under Wash. Rev. Code § 19.86.020.

1594. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Washington Plaintiffs. Ordinary consumers, including Washington Plaintiffs, would have found it material to their purchasing decisions that

the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Washington Plaintiffs', as well as other Washington Subclass members' decision to purchase, lease, or reimburse payment for the Recalled Devices.

1595. Philips owed Washington Plaintiffs and the Washington Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Washington Plaintiffs or Washington Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1596. Washington Plaintiffs, and members of the Washington Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1597. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to Washington Plaintiffs (as set forth above) and members of the Washington Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Washington Plaintiffs and the Washington Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Washington Plaintiffs and Washington Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise

have done. Washington Plaintiffs and Washington Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1598. Accordingly, pursuant to Wash. Rev. Code § 19.86.090, Washington Plaintiffs and Washington Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Washington Plaintiffs and Washington Subclass members are entitled to recover treble damages for the knowing and willful violation of the WCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 70 – VIOLATIONS OF WEST VIRGINIA CONSUMER CREDIT  
PROTECTION ACT**

**W. Va. Code Ann. § 46A-6-101, *et seq.***

**On Behalf of the West Virginia Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1599. Plaintiffs Bays, Hamlin, Rucker, and Ohio Carpenters ("West Virginia Plaintiffs") reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1600. West Virginia Plaintiffs bring this cause of action individually and on behalf of the members of the West Virginia Subclass.

1601. This claim is brought against the Philips Defendants.

1602. The West Virginia Consumer Credit Protection Act (“WVCCPA”) was created to protect West Virginia consumers from deceptive and unfair business practices.

1603. West Virginia Plaintiffs and the West Virginia Subclass members are consumers under the WVCCPA.

1604. West Virginia Plaintiffs and the West Virginia Subclass members purchased, leased, or reimbursed payment for Recalled Devices for personal purposes.

1605. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in West Virginia. In addition, Philips, among other things, sold the Recalled Devices in West Virginia, shipped Recalled Devices to West Virginia, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in West Virginia.

1606. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1607. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was

particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1608. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce in West Virginia, making it unlawful under W. Va. Code Ann. § 46A-6-104.

1609. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have characteristics, ingredients, uses, or benefits, which they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; and (c) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1610. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including West Virginia Plaintiffs. Ordinary consumers, including West Virginia Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in West Virginia Plaintiffs', as well as other West Virginia Subclass members' decision to purchase, lease, or reimburse payment for the Recalled Devices.

1611. Philips owed West Virginia Plaintiffs and the West Virginia Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not West Virginia Plaintiffs or West Virginia Subclass members) who had exclusive and superior

knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1612. West Virginia Plaintiffs, and members of the West Virginia Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1613. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to West Virginia Plaintiffs (as set forth above) and members of the West Virginia Subclass. Absent Defendants' unfair, deceptive and/or fraudulent conduct, West Virginia Plaintiffs and the West Virginia Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced West Virginia Plaintiffs and West Virginia Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. West Virginia Plaintiffs and West Virginia Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1614. Accordingly, pursuant to W. Va. Code § 46A-6-106(a), West Virginia Plaintiffs and West Virginia Subclass members are entitled to recover either: (1) their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence, and those damages are: the difference between the values of the Recalled



Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; or (2) \$200 each, whichever is greater. In addition, given the nature of Philips' conduct, West Virginia Plaintiffs and West Virginia Subclass Members are entitled to recover statutory damages of \$1,000 per violation for the knowing and willful violation of the WVCCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

1615. To the extent that any pre-suit notice was purportedly required, Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. Additional notice letters were served on Philips before this MDL was formed and months before the filing of any Consolidated Class Action Complaint for Economic Losses by plaintiffs who brought putative class actions that have been consolidated in this MDL. These letters put Philips on notice of the demands of the West Virginia Plaintiffs and West Virginia Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate the West Virginia Plaintiffs and West Virginia Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of West Virginia. Finally, notice was provided, and any additional notice would have been futile.

**COUNT 71 – VIOLATIONS OF WISCONSIN DECEPTIVE TRADE PRACTICE ACT**

**Wis. Stat. § 100.18, *et seq.***

**On Behalf of the Wisconsin Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1616. Plaintiffs Matters and MSP (“Wisconsin Plaintiffs”) reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1617. Wisconsin Plaintiffs bring this cause of action individually and on behalf of the members of the Wisconsin Subclass.

1618. This claim is brought against the Philips Defendants.

1619. The Wisconsin Deceptive Trade Practice Act was created to protect Wisconsin consumers from deceptive and unfair business practices.

1620. Wisconsin Plaintiffs and the Wisconsin Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1621. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Wisconsin. In addition, Philips, among other things, sold the Recalled Devices in Wisconsin, shipped Recalled Devices to Wisconsin, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Wisconsin.

1622. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users’ lungs. While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1623. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1624. Philips' conduct described herein with respect to the Recalled Devices constitutes unfair or deceptive acts or practices and untrue, deceptive or misleading representations made in connection with a sale, making it unlawful under Wis. Stat. § 100.18(1)(2)(9).

1625. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Wisconsin Plaintiffs. Ordinary consumers, including Wisconsin Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Wisconsin Plaintiffs', as well as other Wisconsin Subclass members', decision to purchase, lease, or reimburse payment for the Recalled Devices.

1626. Philips owed Wisconsin Plaintiffs and the Wisconsin Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Wisconsin Plaintiffs or Wisconsin Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively

concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1627. Wisconsin Plaintiffs, and members of the Wisconsin Subclass, justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1628. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to Wisconsin Plaintiffs (as set forth above) and members of the Wisconsin Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Wisconsin Plaintiffs and the Wisconsin Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Wisconsin Plaintiffs and Wisconsin Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Wisconsin Plaintiffs and Wisconsin Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1629. Accordingly, pursuant to Wis. Stat. § 100.18(11)(b)(2), Wisconsin Plaintiffs and Wisconsin Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential

damages. In addition, given the nature of Philips' conduct, Wisconsin Plaintiffs and Wisconsin Subclass members are entitled to recover attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

**COUNT 72 – VIOLATIONS OF WYOMING CONSUMER PROTECTION ACT**

**Wyo. Stat. Ann. § 40-12-101, et seq.**

**On Behalf of the Wyoming Subclass, except for Class Members  
who purchased or leased a Recalled Device for business use only**

1630. Plaintiffs reallege and incorporate by reference all preceding allegations as though fully set forth herein.

1631. Plaintiffs bring this cause of action individually and on behalf of the members of the Wyoming Subclass.

1632. This claim is brought against the Philips Defendants.

1633. The Wyoming Consumer Protection Act ("WCPA") was created to protect Wyoming consumers from deceptive and unfair business practices.

1634. Plaintiffs, Wyoming Subclass members, and Philips are all persons under the WCPA.

1635. Plaintiffs and the Wyoming Subclass members purchased, leased, or reimbursed payment for the Recalled Devices for personal purposes.

1636. Philips marketed and advertised the Recalled Devices to consumers, physicians, and other healthcare entities in Wyoming. In addition, Philips, among other things, sold the Recalled Devices in Wyoming, shipped Recalled Devices to Wyoming, and otherwise engaged in trade or commerce, or conducted business, related to the Recalled Devices in Wyoming.

1637. As set forth more fully above, Philips marketed and sold the Recalled Devices as machines that would help users breathe by, among other things, pumping air into users' lungs.

While selling and profiting from the Recalled Devices, Philips knew that they were defective in that they posed serious health risks to users who would potentially be inhaling toxic fumes as they used the machines due to the degradation and off-gassing of the PE-PUR foam. Philips intentionally concealed this material information from consumers, users, payors, prescribers, and other healthcare providers because to do otherwise would have resulted in purchasers and/or users seeking safer alternatives to treat their breathing issues.

1638. Philips concealed and failed to disclose in any of its marketing materials, advertising, packaging, and/or any other communication that the Recalled Devices were defective and would expose users to toxic gas as a result of the degradation and off-gassing of the PE-PUR foam. This material omission was misleading and deceptive standing alone and was particularly deceptive in light of the fact that the Recalled Devices were sold as breathing assistance devices.

1639. Philips' conduct described herein constitutes a violation of several of the provisions enumerated in Wyo. Stat. Ann. § 40-12-105(a) including but not limited to: knowingly engaging in unfair or deceptive acts or practices, misrepresenting the source, nature, quality, condition, or price of merchandise, and advertising good with the intent not to sell them as advertised.

1640. Philips' conduct constituted, among other things, the following prohibited fraudulent, deceptive, and unfair business practices: (a) misrepresenting that the Recalled Devices have uses they do not have; (b) misrepresenting that the Recalled Devices are of a particular standard, quality, or grade, or that goods are of a particular style or model, when they are not; (c) misrepresenting that the Recalled Devices have been supplied in accordance with a

previous representation; and (d) engaging in fraudulent and deceptive conduct that creates a likelihood of confusion and misunderstanding.

1641. Philips' conduct was fraudulent and deceptive because the omissions created a likelihood of confusion and misunderstanding and had the capacity or tendency to deceive and, in fact, did deceive, ordinary consumers, including Plaintiffs. Ordinary consumers, including, Plaintiffs, would have found it material to their purchasing decisions that the PE-PUR foam in the Recalled Devices posed a risk of degradation and off-gassing that would subject users to potential serious health consequences. Knowledge of those facts would have been a substantial factor in Plaintiffs', as well as other Wyoming Subclass members' decision to purchase, lease, or reimburse payment for the Recalled Devices.

1642. Philips owed Plaintiffs and the Wyoming Subclass members, among others, a duty to disclose these facts because they were known and/or accessible exclusively to Philips (along with PolyTech and potentially other unnamed parties who are not Plaintiffs or Wyoming Subclass members) who had exclusive and superior knowledge of the facts; because the facts would be material to reasonable consumers; because Philips actively concealed them; because Philips intended for consumers to rely on the omissions in question; and because the Recalled Devices pose an unreasonable risk of substantial bodily injury.

1643. Plaintiffs and members of the Wyoming Subclass justifiably relied on the material misrepresentations and/or omissions by Philips, and reasonable consumers would have been expected to rely upon these omissions, in part, because they are omissions that impact seriously on a consumer's health and well-being.

1644. Philips' conduct actually and proximately caused actual damages in the form of an ascertainable loss of money or property to Plaintiffs (as set forth above) and members of the

Wyoming Subclass. Absent Philips' unfair, deceptive and/or fraudulent conduct, Plaintiffs and the Wyoming Subclass members would have behaved differently and would not have purchased, leased, or reimbursed payment for the Recalled Devices. Philips' omissions induced Plaintiffs and Wyoming Subclass members to purchase, lease, or reimburse payment for the Recalled Devices, which they would not otherwise have done. Plaintiffs and Wyoming Subclass members acted as reasonable consumers would have acted under the circumstances, and Philips' unlawful conduct would cause reasonable persons to enter into the transactions (purchasing, leasing, or reimbursing payment for the Recalled Devices) that resulted in the damages.

1645. Accordingly, pursuant to Wyo. Stat. Ann. § 40-12-108(a), Plaintiffs and Wyoming Subclass members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence. Those damages are: the difference between the values of the Recalled Devices as represented (their prices) paid and their actual values at the time of purchase or lease (\$0.00), or the cost to replace the Recalled Devices; and other miscellaneous incidental and consequential damages. In addition, given the nature of Philips' conduct, Plaintiffs and Wyoming Subclass members are entitled to statutory, exemplary, treble, and/or punitive damages for the willful and knowing violation of the WCPA and attorneys' fees based on the amount of time reasonably expended and equitable relief necessary or proper to protect them from Philips' unlawful conduct, and all such other relief as the Court deems proper.

1646. To the extent that any pre-suit notice was purportedly required, Plaintiffs have complied or substantially complied with all applicable notice requirements or are otherwise excused from compliance for this proceeding. Philips has had notice of its violations for over a year. In addition, at a minimum, on September 8, 2021, and on May 16, 2022, Plaintiffs involved



in this multi-district litigation, through counsel, sent Philips a letter complying with any required pre-suit notification requirements. These letters put Philips on notice of the demands of the Wyoming Plaintiffs and Wyoming Subclass members, and Philips' responses made clear that Philips refused to acknowledge and cure the violations in a manner that would compensate Wyoming Plaintiffs and Wyoming Subclass members for all the economic losses they have suffered as a result of Philips' misconduct. Philips has failed to remedy its unlawful conduct. In addition, any obligation to provide pre-suit should be excused because Philips does not maintain a place of business or does not keep assets within the state of Wyoming. Finally, notice was provided, and any additional notice would have been futile.

#### **VIII. RELIEF NOT REQUESTED AND RESERVATION OF RIGHTS**

1647. None of the causes of action asserted herein seeks damages or other relief for medical monitoring or personal injuries allegedly attributable to Plaintiffs' and Class members' use of a Recalled Device. Such claims will be governed by the Consolidated Second Amended Class Action (Medical Monitoring) Complaint, to be filed by October 17, 2022, and/or the Amended Master Personal Injury Complaint, to be filed by October 24, 2022, pursuant to the Court's scheduling order (ECF 768), and any additional Short Form complaints that may be filed (or as otherwise agreed by the parties). The named Plaintiffs in this complaint expressly reserve their right to seek damages or other relief for medical monitoring and/or personal injuries they may have suffered, regardless of whether those damages are sought through causes of action alleged herein or otherwise.

#### **IX. PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs request, individually and on behalf of the Nationwide Class and State Subclasses, that this Court:

A. determine that the claims alleged herein may be maintained as a class action under Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Nationwide Class and Subclasses defined above, and designate Plaintiffs as the class and subclass representatives as specified above and Plaintiffs' counsel as counsel for the Nationwide Class and State Subclasses;

B. award equitable relief, including but not limited to, requiring Philips to provide restitution and disgorgement of profits;

C. award all damages to which Plaintiffs and Class members are entitled;

D. award pre-judgment and post-judgment interest on such monetary relief;

E. award reasonable attorneys' fees and costs; and

F. grant such further and other relief that this Court deems appropriate.

#### **X. JURY DEMAND**

Plaintiff and the Class and Subclasses demand a trial by jury on all issues so triable.

Dated: October 10, 2022

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing document was filed via the Court's CM/ECF system on this 10th day of October 2022 and is available for download by all counsel of record.

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